

CHAPTER

5

**Realigning incentives
in Medicare Part D**

R E C O M M E N D A T I O N S

5-1 The Congress should make the following changes to the Part D prescription drug benefit:

- Below the out-of-pocket threshold:
 - Eliminate the initial coverage limit.
 - Eliminate the coverage-gap discount program.
- Above the out-of-pocket threshold:
 - Eliminate enrollee cost sharing.
 - Transition Medicare’s reinsurance subsidy from 80 percent to 20 percent.
 - Require pharmaceutical manufacturers to provide a discount equal to no less than 30 percent of the negotiated price for brand drugs, biologics, biosimilars, and high-cost generic drugs.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 1 • ABSENT 0

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5-2 Concurrent with our recommended changes to the benefit design, the Congress should:

- Establish a higher copayment amount under the low-income subsidy for nonpreferred and nonformulary drugs.
- Give plan sponsors greater flexibility to manage the use of drugs in the protected classes.
- Modify the program’s risk corridors to reduce plans’ aggregate risk during the transition to the new benefit structure.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 1 • ABSENT 0

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5-3 Concurrent with our recommended changes to the benefit design, the Secretary should:

- Allow plans to establish preferred and nonpreferred tiers for specialty-tier drugs.
- Recalibrate Part D’s risk adjusters to reflect the higher benefit liability that plans bear under the new benefit structure.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 1 • ABSENT 0

Realigning incentives in Medicare Part D

Chapter summary

Medicare pays competing private plans to deliver drug benefits to enrolled beneficiaries under Part D. Medicare’s payment system for Part D is different from fee-for-service (FFS) payment systems used under Part A and Part B. For Part D, policymakers envisioned a program that relies on competition among private plan sponsors that bear insurance risk for managing prescription drug use and spending while offering benefit packages that are attractive to enrollees. Instead of setting payments to plans administratively, Medicare’s payments are based on bids submitted by plan sponsors that reflect their average cost (including administrative expenses and an operating margin) of providing a basic outpatient drug benefit to an enrollee of average health.

In the early years of the Part D program, plan sponsors were at risk for a large share of their enrollees’ benefit spending, but that share has declined markedly over time. Between 2007 and 2017, among enrollees without Part D’s low-income subsidy (LIS), the share of basic benefit costs for which plan sponsors were responsible declined from 53 percent to 29 percent. For LIS enrollees, plan liability decreased from 30 percent to 19 percent over the same period. Meanwhile, the Medicare program’s share of benefits reimbursed through two cost-based mechanisms—reinsurance (intended to give plan sponsors some protection against unpredictable variation in costs) and low-income cost-sharing subsidies—rose commensurately. The magnitude of decreases in plans’ share of benefit liability raises significant concerns because it shifts

In this chapter

- Background
- Restructuring Part D to restore incentives to manage spending
- Other modifications to Part D associated with a restructured benefit
- Recommendations for a restructured Part D benefit

substantial financial risk to the Medicare program and taxpayers and undermines a key feature of the Part D program: providing incentives for competing private plans that bear insurance risk for their enrollees' spending to negotiate prices with pharmacies and pharmaceutical manufacturers.

In 2016, the Commission recommended major changes to Part D's benefit structure that would have plan sponsors bear more financial risk for their enrollees' drug spending while, at the same time, providing sponsors with greater flexibility to use formulary tools. The Commission believed that the recommendations would introduce better incentives for plan sponsors to manage drug benefit spending. Since then, changes in law and expanded use of high-priced drugs have further eroded the competitive incentives for cost control and have led the Commission to consider new approaches for restructuring Part D.

Building on the 2016 recommendations, the Commission recommends changes to the Part D program that would restore the role of risk-based, capitated payments that was present at the start of Part D, limit enrollees' out-of-pocket (OOP) spending, and eliminate features of the program that distort market incentives. These reforms will better align the incentives in Part D with the interests of the Medicare program and its beneficiaries. The Commission's package of recommendations would restructure Part D's defined standard benefit as follows:

- For spending below the catastrophic threshold, eliminate the manufacturers' coverage-gap discount that currently applies to enrollees without the LIS and remove the coverage gap for LIS enrollees. These changes would create a standard benefit for all enrollees in which plans would become responsible for 75 percent of spending for benefits between the deductible and the catastrophic threshold, with enrollees responsible for the remaining 25 percent through cost sharing.
- For spending above the catastrophic threshold, reduce Medicare's reinsurance by shifting insurance risk to plan sponsors and drug manufacturers. Medicare would provide 20 percent reinsurance rather than the current 80 percent. Manufacturers would become responsible for at least 30 percent of catastrophic spending on high-priced medicines, while plan sponsors would be liable for the remaining 50 percent. That share is up from the 15 percent of catastrophic benefits that plans cover today. Consistent with our 2016 recommendations, the policy would provide enrollees with greater financial protection by adding an annual cap on beneficiaries' OOP costs.

We recommend that the reduction in Medicare's reinsurance payments and increase in plan liability for catastrophic spending be phased in. (The other elements of

the new benefit structure—eliminating the coverage gap, replacing the coverage-gap discount program with a new discount program in the catastrophic phase, and adding an annual cap on beneficiary OOP costs—would be implemented without a transition.) A longer transition would give plans more time to adjust to the new benefit structure and distribution of risk and allow policymakers to respond to any unexpected outcomes before the new structure is fully phased in. However, it would also leave some of the current system’s misaligned incentives in place longer and potentially inhibit the entrance into the market of new Part D sponsors.

Under the new benefit structure, sponsors would incorporate lower expected Medicare reinsurance subsidies and higher expected benefit liability into plan bids. In turn, Medicare’s capitated payments to plans would increase to incorporate their new, higher share of spending below and above the catastrophic threshold. CMS would also apply risk adjusters to reflect predictable differences in average spending among enrollees based on factors such as age category, disability status, LIS status, and diagnoses.

We recommend a new manufacturers’ discount of at least 30 percent in the catastrophic phase of the benefit. The discount would be more likely to apply to drugs and biologics that command high prices, which could act as a drag on price growth. The discount would apply to LIS beneficiaries as well as to enrollees without the LIS. In addition, the discount could be structured so that if the average price of drugs that were subject to the discount increased faster than a benchmark (such as average Part D spending), the discount rate would increase commensurately.

To help plan sponsors manage overall drug spending more effectively, we recommend that the Congress establish a higher copayment amount under the LIS for nonpreferred and nonformulary drugs. Current LIS copayments provide much weaker financial incentives to choose lower cost medications than those faced by other enrollees. In addition, we recommend that plan sponsors be provided with greater formulary flexibility for drugs in the protected classes. Currently, plan sponsors’ inability to exclude products from a plan’s formulary limits sponsors from using competitive pressure among alternative drug therapies to negotiate manufacturer rebates. We also recommend that plans be allowed to establish preferred and nonpreferred tiers for specialty-tier drugs to encourage their enrollees to use lower priced therapies.

It will be critically important for CMS to recalibrate Part D’s risk adjustment model to reflect the increased plan liability. The Commission’s recommended reforms would result in higher capitated payments for all enrollees, with a larger impact,

in dollar terms, for LIS beneficiaries. Given the structure of the risk adjustment model, we believe that CMS will be able to recalibrate the model to ensure that overall payment rates are adequate for both LIS enrollees and other Part D beneficiaries. Nevertheless, one concern is that because risk adjustment models tend to underpredict very high spending and overpredict very low spending, plans that enroll a relatively large share of high-cost beneficiaries could be disadvantaged. Of particular concern to the Commission are smaller plan sponsors that enroll a high share of LIS beneficiaries.

To examine whether plan sponsors with high shares of LIS beneficiaries are likely to be disadvantaged as a result of inadequate risk adjustment, we compared variation in Part D's gross drug spending for LIS and other Part D beneficiaries. Our findings suggest that, because spending for LIS beneficiaries has relatively less variation than spending for beneficiaries without the LIS, CMS's risk-adjusted payments are less likely to systematically underestimate actual spending for LIS enrollees with very high costs than for other high-cost enrollees. We also separately examined variation in catastrophic spending, which is less easily predicted than spending in the lower phases of the benefit because the extreme values are influenced more heavily by use of high-priced drug and biologic treatments for less-prevalent conditions, such as cancer and rheumatoid arthritis. We found that relative variation around the average was more than twice as large for beneficiaries without the LIS compared with LIS beneficiaries. This difference suggests a recalibrated risk adjustment model would be more likely to underpredict very high spending incurred by beneficiaries without the LIS than it would for beneficiaries with the LIS.

Given plans' greater insurance risk associated with catastrophic spending under these reforms, policymakers could consider modifying the Part D risk corridors to temporarily provide plan sponsors with greater protection during a transition to the new benefit structure. For example, the risk corridors could be narrowed so that plans were fully at risk for less than 5 percent of their aggregate expected benefit costs. Policymakers could also consider different risk-sharing percentages in the corridors, potentially increasing plans' aggregate stop-loss protection (i.e., reducing plans' insurance risk above a threshold). While the enhanced protection would be available to all plans, in practice, the protection would be particularly valuable for smaller plans and plan sponsors that do not have the scale to spread the insurance risk or the capital to reinsure themselves. ■

Background

In 2016, the Commission recommended major changes to the structure of Medicare’s Part D prescription drug benefit to address the misaligned incentives as reflected in patterns of Medicare payments to private plans and plans’ bidding behavior. Those recommendations would have had plan sponsors bear more financial risk for their enrollees’ drug spending while, at the same time, providing sponsors with greater flexibility to use formulary tools (Medicare Payment Advisory Commission 2016).

Since then, changes in law and greater spending for high-priced drugs have led the Commission to consider new approaches for restructuring Part D (Medicare Payment Advisory Commission 2019d). The reforms we recommend in this chapter build on the 2016 package of recommendations, but with two major changes. First, for spending below the catastrophic threshold, we recommend eliminating the manufacturers’ coverage-gap discount that currently applies to enrollees without the low-income subsidy (LIS) and removing the coverage gap for LIS enrollees. These changes would create a standard benefit for all enrollees in which plans would become responsible for 75 percent of benefits between the deductible and the catastrophic threshold, with enrollees responsible for the remaining 25 percent through cost sharing. Second, for spending above the catastrophic threshold, we recommend shifting insurance risk from Medicare to plan sponsors and drug manufacturers. Medicare would provide 20 percent reinsurance rather than the current 80 percent. Manufacturers would become newly responsible for 30 percent or more of catastrophic spending on high-priced medicines, while plan sponsors would be liable for the remaining 50 percent, up from the 15 percent of catastrophic spending they cover today. Consistent with our 2016 recommendations, we also recommend providing enrollees with greater financial protection by adding an annual cap on beneficiaries’ out-of-pocket (OOP) costs.

This chapter also provides an overview of ways in which the program could give plan sponsors greater flexibility to manage formularies, as well as how Part D’s mechanisms for sharing risk might be modified during the transition to a restructured benefit.

Misaligned incentives under Medicare’s payment system for Part D

Medicare’s payment system for Part D is different from fee-for-service (FFS) payment systems used under Part A

and Part B. For Part D, policymakers envisioned a program that relies on competition among private plan sponsors that bear insurance risk for managing prescription drug use and spending while offering benefit packages that are attractive to enrollees. Part D subsidizes basic drug benefits whether a beneficiary is in FFS Medicare and enrolls in a stand-alone prescription drug plan (PDP) or in Medicare Advantage (MA) and enrolls in an MA–Prescription Drug [plan] (MA–PD). Instead of setting payments to plans administratively, Medicare’s payments are based on bids submitted by plan sponsors that reflect their average cost (including administrative expenses and an operating margin) of providing a basic outpatient drug benefit to an enrollee of average health (Medicare Payment Advisory Commission 2019c). Part D includes risk corridors that limit each plan’s overall losses or profits if a plan’s benefit spending is substantially higher or lower than amounts anticipated in the plan’s bid. If plan sponsors are successful at keeping benefit costs below what they bid, they retain most of the difference between payments and actual benefit costs as additional profits. The philosophical foundation of using competing private plans in Part D is reflected in the law’s “noninterference” provision, which explicitly prohibits the Health and Human Services Secretary from “interfer[ing] with the negotiations between drug manufacturers and pharmacies and PDP sponsors.” The law also prohibits the Secretary from “requir[ing] a particular formulary or institut[ing] a price structure for the reimbursement of covered Part D drugs.” (See text box on the Commission’s approach to date with respect to Part D reforms, p. 124.)

Medicare law defines a standard Part D benefit that, for 2020, includes a \$435 deductible and 25 percent coinsurance until the enrollee reaches an OOP threshold (at roughly \$9,000 to \$10,000 in gross drug spending).¹ Above this threshold, enrollees generally pay 5 percent coinsurance with no upper limit on their annual cost-sharing liability. Most plan sponsors structure their basic benefits in ways that differ from the defined standard benefit, but sponsors must demonstrate that those alternative benefit structures have the same average value as the defined standard benefit. Medicare provides two types of subsidies to plans on behalf of all Part D enrollees: (1) monthly capitated payments adjusted for risk and (2) individual reinsurance equal to 80 percent of prescription costs above the OOP threshold (net of postsale rebates). Medicare’s subsidies aim to cover 74.5 percent of the cost of basic benefits, with enrollee

The Commission's approach to Part D reform

Policy makers structured the Part D program using private plans that compete to attract enrollees based on the prescription drugs they cover, pharmacy networks, premiums, cost sharing, and quality of services. Plan sponsors negotiate with pharmacies over reimbursement rates for prescriptions filled by their enrollees, as well as with pharmaceutical manufacturers for postsale rebates. Under current Part D law, the federal government may not interfere in those private negotiations, establish a specific formulary, or set prices for drugs.

To date, the Commission has not recommended measures that would require altering this basic approach. In keeping with the program's original philosophy, the Commission's 2016 recommendations would modify the benefit design and structure of Medicare subsidies to strengthen the incentives of

private entities involved in negotiating drug prices (Medicare Payment Advisory Commission 2016). Similarly, our recommendations in this chapter aim to restore the role of risk-based, capitated payments that was present at the start of Part D and eliminate features of the program that distort market incentives.

Nevertheless, the Commission intends to continue monitoring growth in drug prices and monitoring the implications of that growth for beneficiaries' access to biopharmaceutical therapies and for taxpayers. The premise behind Part D's competitive approach is that plan sponsors can negotiate for lower prices because manufacturers are offering competing drug therapies. In therapeutic classes where such competition is weak or does not exist, private plans have little or no bargaining leverage with manufacturers for price reductions. Other policy approaches may be needed to address those circumstances. ■

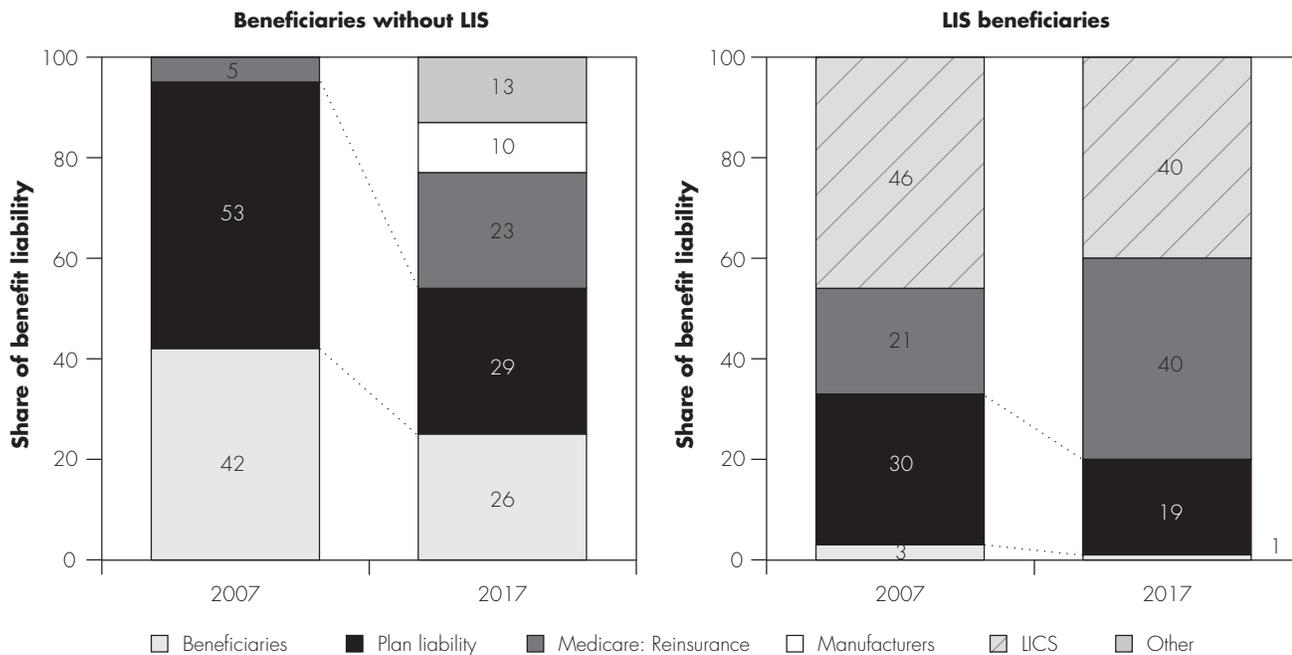
premiums covering the remaining 25.5 percent. Premiums for plans vary individually, however, depending on how high or low their sponsor bids and whether they offer supplemental coverage (which Medicare does not subsidize).

The Part D benefit also includes the LIS to ensure that poorer beneficiaries have sufficient access to drug coverage. Beneficiaries qualify for the LIS if they are eligible for any type of Medicaid benefits or have income below 150 percent of the federal poverty guideline and limited assets.² In 2019, 28 percent of Part D enrollees received the LIS, most of whom were Medicare–Medicaid dual-eligible beneficiaries. Part D's LIS has two components: premium subsidies and cost-sharing subsidies. The low-income cost-sharing subsidy (LICS) makes up more than 85 percent of combined LIS spending. CMS makes monthly prospective payments to plans for both LIS premium subsidies and the LICS. Payments for the latter are based on plan estimates and are later reconciled to actual costs after the end of each plan year.

In keeping with Part D's market-based approach, in the early years of the program, plan sponsors were at risk for a large share of their enrollees' benefit spending. However, over the past decade, the share of benefit costs borne by plan sponsors has declined markedly. Figure 5-1 displays estimates of Part D spending, net of rebates, for basic benefits for enrollees with and without the LIS. The estimates reflect spending amounts on Part D claims minus average rebates as reported by the Medicare Trustees (Boards of Trustees 2019). Between 2007 and 2017, among enrollees without the LIS, the share of basic benefit costs for which plan sponsors were responsible declined from 53 percent to 29 percent. For LIS enrollees, plan liability decreased from 30 percent to 19 percent over the same period. Meanwhile, the Medicare program's share of benefits reimbursed through two cost-based mechanisms—reinsurance and LICS—rose commensurately. The magnitude of decreases in plans' share of benefit liability raises significant concerns because it undermines key features of the Part D program: competing private entities that bear financial risk for their enrollees' spending.

FIGURE 5-1

Plans' share of benefit liability declined markedly between 2007 and 2017



Note: LIS (low-income subsidy), LICS (low-income cost-sharing subsidy). Estimated spending net of all rebates and discounts. Figures assume that the percentage reduction in total spending attributable to rebates and discounts does not differ systematically between beneficiaries with the LIS and those without the LIS. Components may not sum to 100 percent due to rounding. The “other” figures include payments by patient assistance organizations and third-party payers, other than Part D plans, that reduce beneficiary cost-sharing liability (such as employers who provide supplemental coverage to retirees).

Source: MedPAC based on Part D prescription drug event data and aggregate direct and indirect remunerations from the Medicare Trustees (Boards of Trustees 2019).

Low plan liability and expanded use of high-cost medicines have eroded incentives to manage spending

Changes in Part D law that financed the phase-out of the coverage gap through brand manufacturer discounts and the expanded use of high-cost medicines have reduced plans' liability for benefit spending, thereby eroding plans' incentives to manage spending.

Changes to Part D's coverage gap

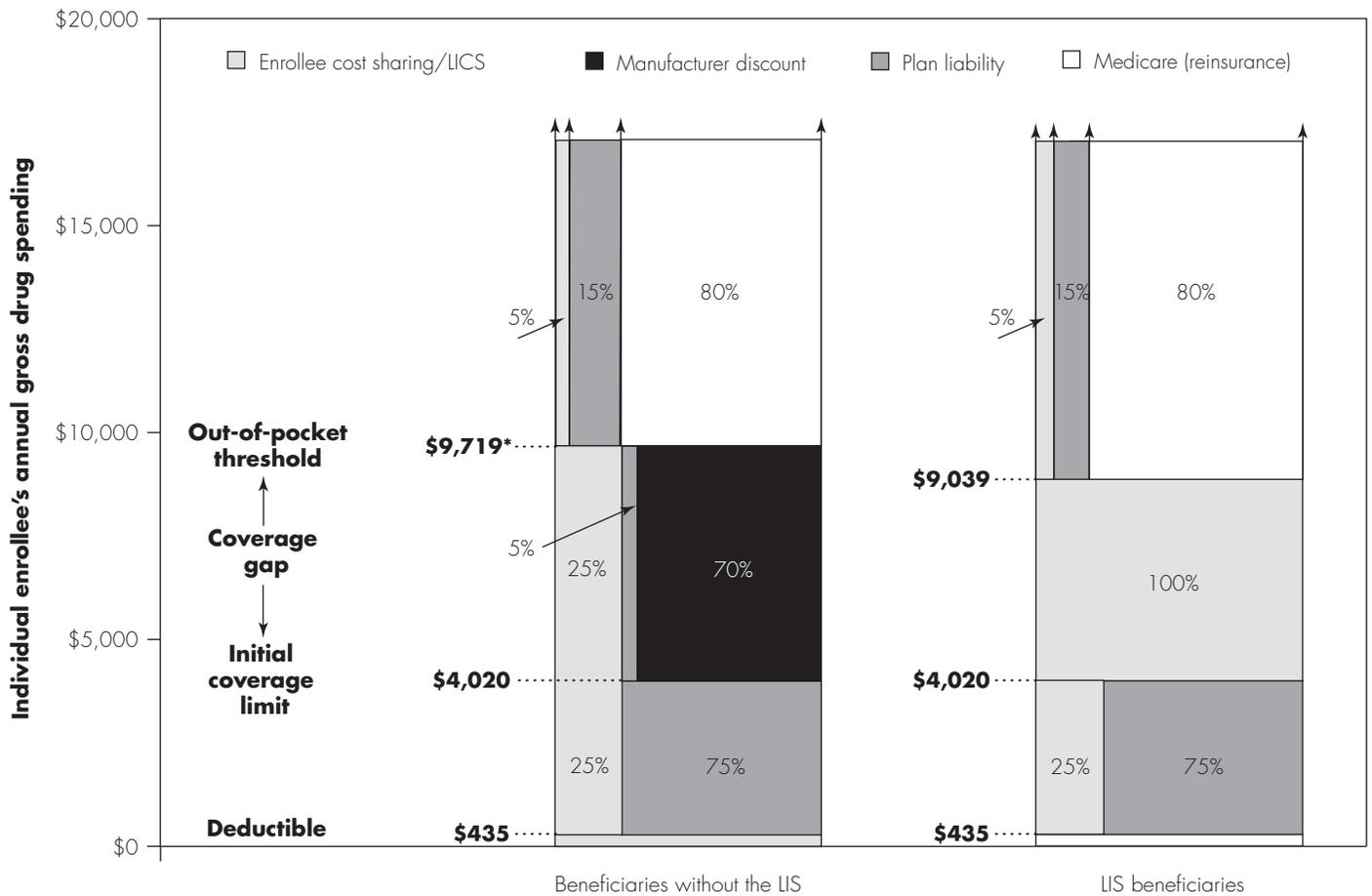
Part D's defined standard benefit covers 75 percent of drug spending above the deductible and all but 5 percent coinsurance once an enrollee reaches the OOP threshold (Figure 5-2, p. 126). That threshold is based on “true OOP” costs because it excludes beneficiary cost sharing paid by most sources of supplemental coverage, such as employer-sponsored policies and enhanced benefits. For

LIS enrollees, Medicare's LICS pays for the difference between the cost-sharing amounts in the plan's formulary and nominal copayments set by law (Figure 5-2).

Before 2011, enrollees who did not receive the LIS and had spending that exceeded an initial coverage limit were responsible for paying each subsequent prescription's full price at the pharmacy (i.e., 100 percent cost sharing) until they reached the OOP threshold. This is known as the coverage gap. Even today, when the defined standard benefit has 25 percent coinsurance in both the initial coverage phase and coverage-gap phase, many Part D plans structure their cost sharing differently across the two phases, with copayments for generics and preferred drugs initially, but 25 percent coinsurance in the coverage gap. For LIS enrollees, Part D's LICS pays for all coverage-gap spending other than nominal copayments set by law.

FIGURE 5-2

Part D has two distinct benefit structures for enrollees with and without the LIS



Note: LIS (low-income subsidy), LICS (low-income cost-sharing subsidy). For beneficiaries without the LIS (left bar), the coverage gap (between the initial coverage limit and the out-of-pocket (OOP) threshold) is depicted as it would apply to brand-name drugs. Plan sponsors pay 75 percent of the cost of generic prescriptions filled in the coverage-gap phase for beneficiaries without the LIS. For LIS beneficiaries, Medicare’s low-income cost-sharing subsidy pays for all spending in the coverage gap except LIS enrollees’ nominal copayments. In 2018, the total amount of cost sharing paid directly OOP by LIS beneficiaries accounted for about 1 percent of total gross spending.

*Total covered drug spending at the annual OOP threshold for beneficiaries who do not receive the LIS depends on the mix of brand and generic drugs filled in the coverage gap. The dollar amount shown (\$9,719) was estimated by CMS for an individual with an average mix of drugs who does not receive Part D’s LIS and has no other supplemental coverage.

Source: MedPAC depiction of Part D benefit structure for 2020 as set by law.

Manufacturer discounts in the coverage gap distort market incentives The Affordable Care Act of 2010 (ACA) and the Bipartisan Budget Act (BBA) of 2018 expanded Part D’s defined standard benefit to gradually eliminate the coverage gap for enrollees without the LIS. As shown in Figure 5-2, this expansion left two distinct benefit structures in Part D: one for enrollees without the LIS and one for enrollees with the LIS. Much of this benefit expansion was financed by requiring brand-name

drug manufacturers to discount prices in the coverage gap. While the phase-out of the coverage gap lowered OOP costs for some beneficiaries, the manufacturer discount artificially lowered the price of brand-name drugs relative to generics, reducing incentives to use generics.

Those incentives are further undermined because the 70 percent manufacturer coverage-gap discount on brand-name drugs is treated as though it were the enrollee’s own spending. Thus, enrollees without the LIS reach

Part D's catastrophic phase more quickly when they use brand-name drugs than when they use generic drugs. Manufacturers of brand-name drugs benefit when enrollees reach the catastrophic phase because they are no longer required to discount prices.

Plan sponsors must cover 75 percent of generic spending but just 5 percent of brand spending in the coverage gap while also receiving postsale rebates and discounts on some brand prescriptions. Sponsors cover 15 percent of all spending (generic or brand) in the catastrophic phase. CMS's Office of the Actuary projects that, in 2020, plan sponsors will obtain postsale rebates and discounts worth about 28 percent of total drug costs (Boards of Trustees 2019). For some brand-name drugs, the value of rebates and discounts can exceed plan liability in both the coverage-gap and catastrophic phases of the benefit. For some products, plan sponsors may find that including a brand-name drug on their formulary rather than a generic or giving the brand preferred status lowers their plan liability. However, those formulary placement decisions also increase costs for enrollees and Medicare (Dusetzina et al. 2019). CMS raised concern about the effects of the coverage-gap discount and low plan liability in two recent call letters to plan sponsors (Centers for Medicare & Medicaid Services 2019a, Centers for Medicare & Medicaid Services 2018a).

Benefit design for LIS enrollees creates little incentive for cost control For LIS enrollees, the ACA retained Part D's original defined standard benefit structure, with no plan liability in the coverage-gap phase and no brand discount from manufacturers. Instead, coverage-gap costs are borne almost entirely by the Medicare program. Part D's LICS reimburses plan sponsors for the difference between 100 percent cost sharing and LIS enrollees' nominal copayments. Because 100 percent of the costs in the coverage gap count toward the OOP threshold, LIS beneficiaries reach the catastrophic phase of the benefit at a lower level of spending than other enrollees do.

The LIS benefit structure shares a common feature with the benefit design for other enrollees in that plan sponsors bear little or no liability for spending in the coverage-gap phase. For LIS enrollees, plans bear zero benefit liability, yet sponsors receive postsale rebates on some brand-name prescriptions. That means brand prescriptions filled by LIS enrollees in the coverage gap can be profitable for plan sponsors, undermining incentives for cost control. At the same time, because Medicare's LICS covers most

cost sharing, LIS beneficiaries have little incentive to use lower cost drugs. These features may be reasons why LIS enrollees use more brand-name drugs even when generic alternatives are available.

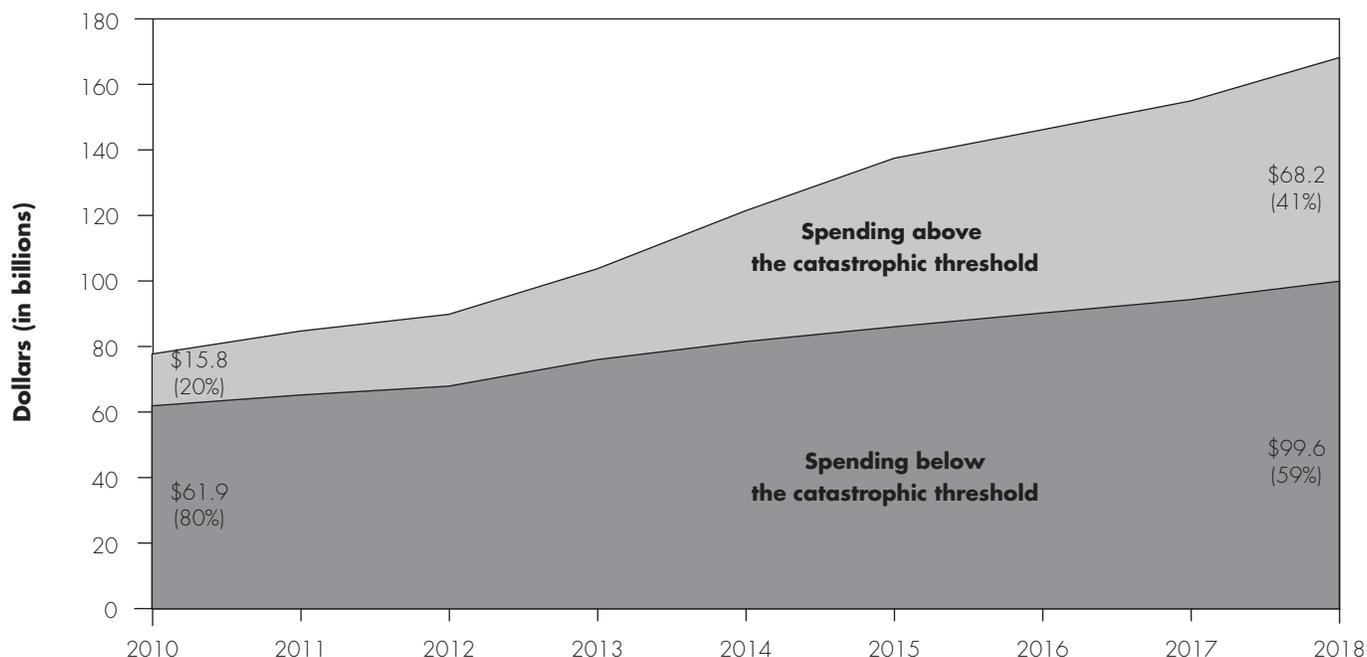
Expanded role of high-priced drugs drives growth in reinsurance

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, and hypertension (Medicare Payment Advisory Commission 2010). Most prescription spending was for small-molecule brand-name drugs that competed with other therapies based on clinical effectiveness and price.

Beginning around 2010, a number of blockbuster treatments began to lose patent protection, and many Part D enrollees switched to generic versions of their medicines (Medicare Payment Advisory Commission 2017). 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, hepatitis C, and cancer. Those medicines are often launched at very high prices, with annual costs per person sometimes reaching tens of thousands of dollars or more. List prices for many existing brand-name therapies increased at a rapid pace as well.

By law, CMS increases Part D's OOP threshold annually at the same rate as the annual change in enrollees' average drug expenses. Between 2006 and 2018, increased generic use helped to keep growth in average Part D drug expenses to about 4 percent per year (Medicare Payment Advisory Commission 2019e). However, prices of brand-name drugs and biologics grew at a much faster rate over the same period—more than 7 percent annually.³ As a result, an increasing share of spending for high-priced, brand-name products is in Part D's catastrophic phase, where Medicare pays 80 percent of the costs through reinsurance and plans bear just 15 percent benefit liability.

Before 2010, less than 20 percent of spending was for prescriptions filled in the catastrophic phase of the Part D benefit. Since 2010, catastrophic spending has more than quadrupled. As a result, catastrophic spending's share of total spending increased from 20 percent in 2010 to 41 percent in 2018 (Figure 5-3, p. 128).

**FIGURE
5-3****The proportion of gross Part D spending made up by catastrophic benefits more than doubled, 2010-2018**

Note: Catastrophic benefits are defined as enrollee spending above Part D's out-of-pocket threshold. "Gross Part D spending" refers to amounts paid at the pharmacy before postsale rebates and discounts.

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

Higher prices, reflecting both increases in prices of existing products and the use of new high-priced drugs, are the primary driver of the rapid growth in catastrophic spending. Between 2010 and 2017, the average price per standardized, 30-day prescription filled by beneficiaries who reached the catastrophic phase grew by 9.4 percent per year, while the number of prescriptions filled per enrollee remained flat. This growth rate is in stark contrast to enrollees who did not reach the catastrophic phase: Their average price per prescription fell by an annual rate of 2.9 percent, while the number of prescriptions filled per enrollee grew by 1.3 percent per year.

Part D's benefit design contributes to the inflationary trend in drug prices

While Medicare's influence on drug pricing is indirect, the program accounts for about one-third of U.S. retail pharmaceutical sales (Hartman et al. 2019). As a result,

Medicare's payment policies can have a significant financial effect on drug manufacturers. High drug prices are not unique to Part D. However, for medications that are more likely to be used by Medicare beneficiaries, the Commission has been concerned that the program's orientation toward premium competition and Part D's unique benefit design may contribute to higher prices (Medicare Payment Advisory Commission 2017).

One concern is that Part D plan sponsors' focus on rebates has been inflationary. In drug classes that have competing therapies, plan sponsors negotiate with brand manufacturers for rebates that are paid after a prescription has been filled. Generally, manufacturers pay larger rebates when a plan sponsor positions a drug on its formulary in ways that increase the likelihood that the manufacturer will win market share over competitors. Rebates are often calculated as a percentage of a drug's

list price, and thus higher prices can lead to a higher dollar amount of rebates. Moreover, when plan sponsors negotiate a “price protection” provision, rebates are linked directly to manufacturers’ price increases (Kaczmarek 2015, Pharmacy Benefit Management Institute 2017). Sponsors may be less resistant to manufacturers’ price increases for brand medications when there are rebates to offset some or all the plan’s benefit liability.

In many situations, plan sponsors focus on rebates to keep their premiums competitive; they generally use rebate revenues to offset aggregate benefit costs and thereby lower their premiums. Using rebates to offset the cost of aggregate benefits may also increase the likelihood of retaining profits in Part D’s risk corridors (Walker and Weaver 2019). However, beneficiaries pay coinsurance based on point-of-sale (POS) prices—those prices at the pharmacy counter before postsale rebates and discounts. In turn, beneficiaries reach Part D’s OOP threshold more quickly than if coinsurance were charged on net prices. Similarly, the Medicare program pays more in reinsurance and LICS than it would if there were a smaller difference between POS and net prices (Centers for Medicare & Medicaid Services 2017).

Part D’s unique structure can also contribute to inflationary trends in drug prices. Part D’s benefit design can create incentives to include high-cost, high-rebate drugs on formularies over other drugs because plan sponsors bear relatively little liability for benefit spending in the coverage gap and catastrophic phase (Fein 2020). 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 addition, because coverage-gap discounts apply to a limited range of spending (between the initial coverage limit and the OOP threshold), a manufacturer’s liability for any given beneficiary is capped. In 2020, the maximum amount any brand manufacturer would pay is about \$4,000 per beneficiary regardless of the price it charges for its product. As a result, if a manufacturer can raise the prices of its products, that increase could offset some or all of the costs associated with the coverage-gap discounts.

Policymakers’ decisions about the amount that manufacturers must pay in coverage-gap discounts may have factored into manufacturers’ decisions about price increases or launch prices, especially for drugs that have

relatively low prices because coverage-gap discounts affect a proportionately larger share of manufacturers’ revenues. For drugs and biologics with prices near or above the catastrophic threshold, manufacturer discounts in the coverage gap are small compared with their revenue from Part D prescriptions (Table 5-1, p. 130). For example, based on 2018 data, gross spending (before postsale rebates and discounts) for Revlimid[®], a chemotherapy drug used for certain cancers, totaled \$4.1 billion. The coverage-gap discount paid by Revlimid’s manufacturer totaled about \$77 million, or 1.9 percent of gross spending. Because the majority (86 percent) of spending for Revlimid occurred in the catastrophic phase of the benefit (above the OOP threshold), the coverage-gap discount applied to the less than 4 percent of spending that fell in the coverage gap. In comparison, about 75 percent of spending for Lantus Solostar[®] (a type of insulin) occurred below the OOP threshold. The coverage-gap discount for Lantus Solostar totaled \$203 million in 2018, or 8.6 percent of the \$2.4 billion in gross spending for this product.

Restructuring Part D to restore incentives to manage spending

In its June 2019 report, the Commission discussed changes to Part D that would simplify the benefit for all enrollees and restore incentives for plans to manage drug spending (Medicare Payment Advisory Commission 2019d). Below the OOP threshold, the new standard benefit would have no coverage gap, making plans responsible for 75 percent of spending between the deductible and the start of the catastrophic phase for all enrollees (Figure 5-4, p. 131). To carry out this change, Part D would eliminate the coverage-gap discount program for enrollees without the LIS and eliminate the coverage gap for LIS enrollees. Above the OOP threshold, consistent with our 2016 recommendations, the policy would provide enrollees with greater financial protection by adding an annual cap on OOP spending. The policy would also phase in a shift of insurance risk from Medicare to plan sponsors and drug manufacturers.

Under the redesigned Part D benefit, Medicare would make larger capitated payments to plan sponsors, with the overall subsidy rate remaining unchanged at 74.5 percent. That is, Medicare’s total payments to plans for the basic benefit would remain unchanged if there were

**TABLE
5-1**

The coverage-gap discount affected a smaller share of spending for higher priced drugs and biologics, 2018

Brand name	Therapeutic class	Total gross spending (in billions)	Coverage-gap discount		Average gross spending per prescription	Share of gross spending above OOP threshold
			Amount (in millions)	As share of total gross spending		
Examples of higher priced drugs and biologics						
Revlimid®	Antineoplastic	\$4.1	\$77	1.9%	\$14,217	86%
Harvoni®	Antiviral	1.7	17	1.0	31,673	89
Humira pen®	Analgesics, anti-inflammatory	2.4	57	2.4	6,053	78
Copaxone®	Multiple sclerosis agent	1.2	28	2.3	6,524	83
Examples of other drugs and biologics						
Lantus Solostar®	Diabetic therapy	\$2.4	203	8.6%	\$530	25%
Eliquis®	Anticoagulant	5.0	541	10.8	549	10
Advair Diskus®	Respiratory therapy agent	2.4	159	6.6	544	16
Lyrica®	CNS agent	3.0	188	6.4	565	28

Note: OOP (out-of-pocket), CNS (central nervous system). "Gross spending" refers to amounts paid at the pharmacy before postsale rebates and discounts.

Source: MedPAC analysis of 2018 Part D prescription drug event data.

no behavioral responses by plan sponsors, manufacturers, or beneficiaries. In practice, because plan sponsors would be liable for a greater share of spending both above and below the OOP threshold, the policy would likely change plan sponsors' formulary incentives and their negotiations with manufacturers over rebates. For example, we anticipate that it would be difficult for manufacturers of high-priced products to offer rebates large enough to make their products financially advantageous for plan sponsors when lower cost products are available. As a result, plan sponsors would likely prefer lower priced products among therapeutic alternatives rather than high-priced, high-rebate products. That change, in turn, would reduce the financial benefit of higher prices for some manufacturers. Collectively, our reforms eliminating the coverage gap and restructuring Part D's catastrophic benefit would involve several policy changes.

Eliminate the coverage gap

The policy to eliminate the coverage gap would discontinue manufacturer discounts below Part D's catastrophic threshold and establish a single defined standard benefit structure for all enrollees.

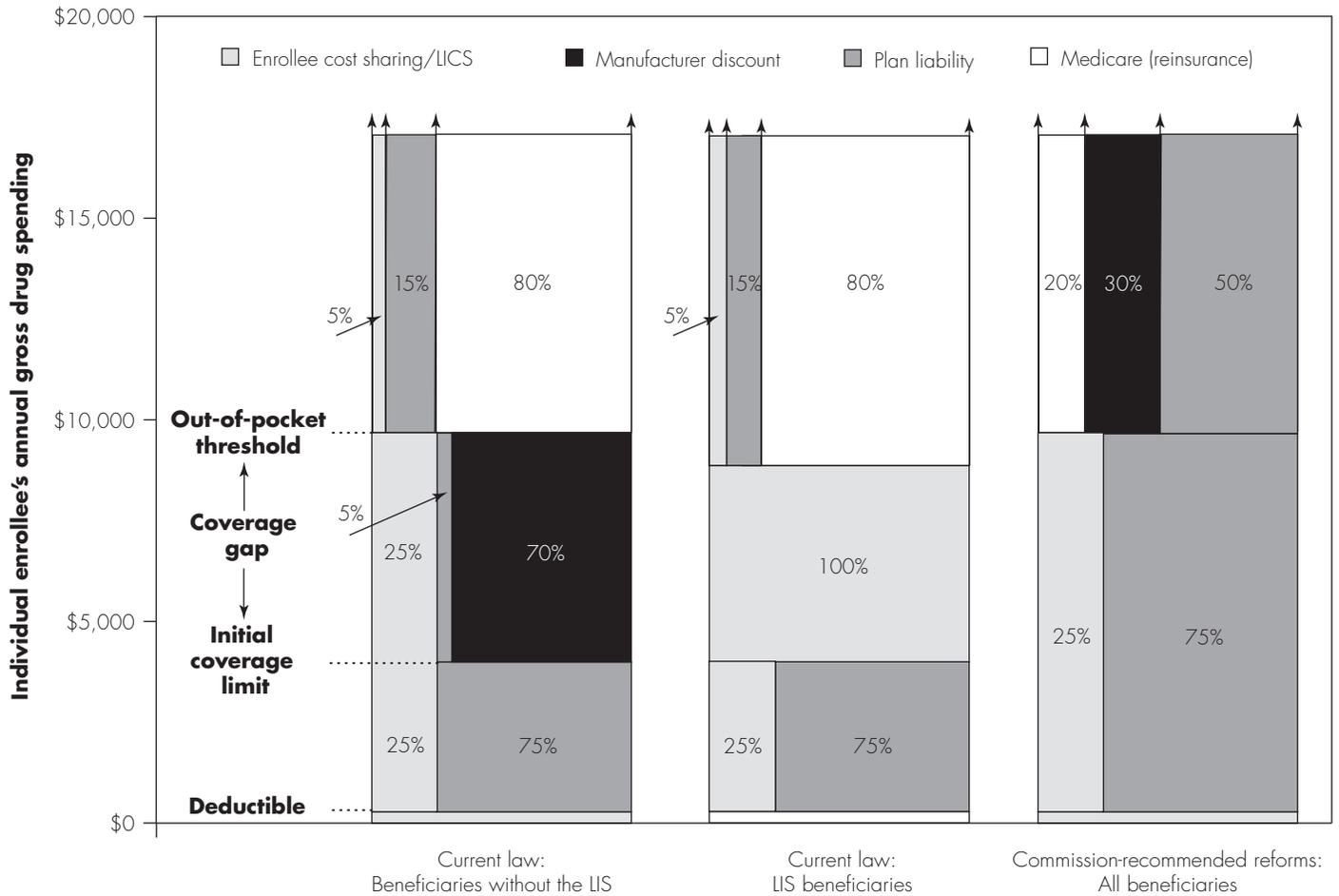
Discontinue brand manufacturer discounts below the catastrophic phase

Discontinuing brand manufacturer discounts below the catastrophic phase would simplify Part D's benefit structure by making plans responsible for a consistent 75 percent of benefits between the deductible and the OOP threshold. Under this change, the price of brand-name drugs would no longer be artificially lowered relative to generics. Plans would have much less incentive to place high-priced, highly rebated drugs on their formularies, while enrollees without the LIS would face stronger incentives to use lower cost products, potentially reducing Part D costs over the longer term.

Absent other changes, removing the coverage-gap discount would increase benefit costs. For example, in 2018, brand discounts totaled nearly \$7 billion which, under a restructured benefit, plans would have paid instead of manufacturers. (If the coverage-gap discount rate had been 70 percent in 2018 as it was in 2019 and subsequent years, we estimate that the discount amount would have been over \$9 billion.) Under the restructuring of Part D's catastrophic benefit, new manufacturer discounts in

FIGURE 5-4

The Commission’s recommended Part D reforms would simplify Part D’s benefit structure and give plans stronger incentives to manage drug spending



Note: LICS (low-income cost-sharing subsidy), LIS (low-income subsidy). The coverage gap for enrollees without the LIS (between the initial coverage limit and spending at the out-of-pocket (OOP) threshold) is depicted as it would apply to brand-name drugs. For generic prescriptions filled by enrollees without the LIS, cost sharing in the coverage gap is 25 percent and plans are responsible for 75 percent. For LIS enrollees, Medicare’s low-income cost-sharing subsidy pays for all spending in the coverage gap except LIS enrollees’ nominal copayments.

Source: MedPAC depiction of Part D’s benefit structure under current law and under the Commission’s recommended reforms.

the catastrophic phase could replace the coverage-gap discount and thereby offset increased benefit costs.

Plans become responsible for LIS enrollees’ coverage-gap spending

By eliminating the coverage gap for LIS beneficiaries, plans would become responsible for 75 percent of LIS enrollees’ spending between the deductible and the OOP threshold. Because cost sharing for LIS enrollees is limited

to nominal copayments, Medicare’s LICS would cover most or all of the 25 percent cost sharing that enrollees without the LIS pay themselves. The policy change would improve plan sponsors’ formulary and cost-control incentives. However, because much of what is currently covered by the LICS would become part of the basic benefit design, absent other changes, the new approach would also lead to higher costs for the basic benefit and higher premiums for all Part D enrollees.

**TABLE
5-2**

Financial impact of eliminating the coverage gap for LIS enrollees, 2018

	Financial impact (in billions)
Total low-income cost-sharing subsidy in the coverage gap in 2018	\$13.0
New plan liability under a consistent benefit structure for enrollees with and without LIS (roughly 75% of the \$13 billion)	\$10.0
Medicare’s payments to plans (74.5%)	\$7.5
Enrollee premiums (25.5%)	\$2.6
Total	\$10.0
Effects on Medicare program spending	
Increase in payments to plans for higher benefit costs	\$7.5
Increase in payments for low-income premium subsidy	\$0.8
Reduction in payments for low-income cost-sharing subsidy	-\$10.0
Net effect	-\$1.8

Note: LIS (low-income subsidy). Components may not sum to totals because of rounding. The low-income cost-sharing subsidy is one component of LIS spending that pays for the difference between the amount of cost sharing charged by a plan and the LIS copayment amount set by law. The other component of LIS spending is the low-income premium subsidy—Medicare payments that cover most or all of the premium (up to a dollar limit that varies by region) on behalf of LIS enrollees.

Source: MedPAC estimate based on Part D prescription drug event data.

To evaluate the effects of this change, we started with an estimate of LIS spending for prescriptions filled in the coverage gap—about \$13 billion in 2018.⁴ Under a revised benefit structure, the basic Part D benefit would cover 75 percent, or about \$10 billion, of LIS enrollees’ spending in the coverage gap as currently defined (Table 5-2). Of that \$10 billion, Medicare’s subsidy payments to plans for all Part D enrollees would increase by about \$7.5 billion and the remaining \$2.6 billion would be paid in the form of higher enrollee premiums, which would increase by an average of about \$4.80 per month. However, other elements of a restructured benefit, such as the manufacturer discount in the catastrophic phase, could offset some of this premium increase. Of the \$2.6 billion in enrollee premiums, \$0.8 billion would be paid by Medicare for Part D’s LIS enrollees, with the remaining \$1.8 billion borne by Part D enrollees without the LIS. Assuming no behavioral changes, the financial impact for Medicare in this example would be the net effect of higher payments to plans for the basic Part D benefit (\$7.5 billion) and higher LIS spending on premiums (\$0.8 billion), offset by \$10 billion in lower LIS spending. Combined, there would be a net reduction in Medicare program spending of \$1.8 billion.

Restructure Part D’s catastrophic benefit

The Commission’s recommendations to restructure the catastrophic benefit would eliminate beneficiary cost sharing in the catastrophic phase (thereby creating an annual cap on OOP costs) and lower Medicare’s reinsurance in favor of manufacturer discounts and greater plan liability.

Eliminate beneficiary cost sharing in the catastrophic phase

In 2018, 3.9 million, or 8.3 percent, of Part D enrollees reached Part D’s OOP threshold. Among those individuals, 2.7 million (70 percent) received the LIS and 1.1 million did not (Table 5-3). LIS enrollees are much more likely than other enrollees to reach the catastrophic phase of the benefit (19 percent vs. 3 percent, data not shown), reflecting their higher average drug spending. Individuals who have high spending and do not receive the LIS pay 5 percent coinsurance on prescriptions in the catastrophic phase with no limit on annual OOP costs.⁵ In 2018, spending on the 5 percent coinsurance for those enrollees amounted to \$1.3 billion. LIS enrollees who have high spending are also subject to 5 percent coinsurance in the

**TABLE
5-3**

Part D enrollees reaching the benefit's catastrophic phase, 2015-2018

	2015	2016	2017	2018	AAGR, 2015-2018
Number of enrollees reaching OOP threshold (in millions)					
LIS enrollees	2.6	2.6	2.6	2.7	1.3%
Enrollees without LIS	<u>1.0</u>	<u>1.1</u>	<u>1.0</u>	<u>1.1</u>	<u>3.3%</u>
All	3.6	3.6	3.6	3.9	1.9%
Share of all Part D enrollees	8.7%	8.3%	8.0%	8.3%	N/A
Cost-sharing liability in the catastrophic phase (in billions)					
LIS enrollees	\$1.7	\$1.8	\$1.9	\$2.1	1.3%
Enrollees without LIS	<u>0.9</u>	<u>1.0</u>	<u>1.1</u>	<u>1.3</u>	<u>12.7%</u>
Total	2.6	2.8	3.0	3.4	9.9%

Note: AAGR (average annual growth rate), OOP (out-of-pocket), LIS (low-income subsidy), N/A (not applicable). Components may not sum to totals due to rounding.

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

catastrophic phase, but their cost-sharing obligation is fully covered by Medicare's LICS. For LIS enrollees, in 2018, Medicare's LICS paid about \$2.1 billion for coinsurance in the catastrophic phase.

Under a restructured Part D benefit, beneficiaries would have no cost-sharing liability in the catastrophic phase, providing complete financial protection to enrollees once they reached the OOP threshold (consistent with our 2016 recommendation). This protection would be particularly valuable for beneficiaries with the highest spending who do not receive the LIS. For example, in 2018, of the 1.1 million high-spending enrollees without the LIS, about 110,000 paid \$2,800 or more in cost sharing for prescriptions filled in the catastrophic phase of the benefit.

Under current law, in 2020, the catastrophic phase starts when an enrollee accrues \$6,350 in OOP costs, but brand manufacturer discounts in the coverage gap count toward that amount. A beneficiary who takes the average mix of generic and brand-name drugs would reach that threshold by spending about \$2,750 of their own money and would receive \$3,600 in manufacturer discounts. Beneficiaries who use a higher than average share of generic drugs would need to spend more of their own money to reach the OOP threshold. If the coverage-gap

discount were eliminated in 2020, beneficiaries without the LIS, regardless of their mix of brand-name and generic drugs, would have to pay the full \$6,350 to reach the OOP threshold. For this reason, policymakers could consider a lower catastrophic threshold under a restructured benefit to ensure that beneficiary OOP spending does not exceed the level it would have been had the coverage-gap discount remained.

Eliminating cost sharing in the catastrophic phase would result in higher benefit costs. For example, in 2018, the \$3.4 billion in cost sharing that was paid by enrollees without the LIS and by Medicare's LICS for LIS enrollees would instead have been included in plan bids. In turn, premiums for all Part D enrollees would have increased by roughly \$1.60 per month. Medicare's spending to subsidize the basic Part D benefit for all enrollees would increase by \$2.5 billion (74.5 percent of \$3.4 billion). In the aggregate, premiums would increase by \$0.9 billion, with about \$0.3 billion of that amount covered by Medicare's premium assistance for LIS enrollees. In addition, the policy would likely increase prescriptions filled in the catastrophic phase of the benefit by beneficiaries without the LIS. As a result, effects on Medicare's subsidy payments for Part D's basic benefit costs and enrollee premiums would likely be higher than

the static estimate that assumes no behavioral response. Policymakers could require manufacturers of brand-name drugs to provide a somewhat higher discount in the catastrophic phase to pay for the new financial protections provided to high-cost enrollees. The net effect on Medicare program spending would be an increase of \$0.7 billion (\$2.5 billion in higher spending on the basic benefit and \$0.3 billion in higher LIS spending on premiums, minus \$2.1 billion in lower LICS spending).

Establish a manufacturer discount in the catastrophic phase

In its June 2019 report, the Commission discussed converting the coverage-gap discount to a discount in Part D's catastrophic phase as a way to provide plan sponsors and manufacturers with better formulary and pricing incentives (Medicare Payment Advisory Commission 2019d). In the recommendation described here, the manufacturer discount would apply to prescriptions in the catastrophic phase for both brand-name drugs and biologics (including biosimilars) and generic prescriptions to reach CMS's threshold to be placed on a specialty tier (with an average price of \$670 per month or more in 2020). The manufacturer discount would apply to prescriptions filled in the catastrophic phase by LIS beneficiaries as well as beneficiaries without the LIS.

Compared with the current discount in the coverage gap, a manufacturers' discount in the catastrophic phase would apply more directly to drugs and biologics that command high prices, potentially acting as a drag on price growth. Because the dollar amount of the discount would increase proportionately with the price of the drug, high-priced products would be subject to a larger financial liability than lower priced products. Compared with a manufacturer discount in the coverage-gap phase, some analysts believe that a discount in the catastrophic phase could make the prospect of raising prices less attractive for manufacturers. Others believe that manufacturers would launch new drugs at prices high enough to compensate for the discount liability. The extent to which manufacturers could increase prices or launch new drugs at higher prices would vary by product and would depend on multiple factors, including the degree of competition within a therapeutic class and Medicare's market share of that product. Policymakers could structure the discount so that if average prices of drugs subject to the discount increased faster than a benchmark (such as average Part D spending), the discount rate would increase commensurately.

In 2018, if the coverage-gap discount rate had been 70 percent (as was the case in 2019 and subsequent years), manufacturer discounts would have totaled about \$9 billion. Based on the distribution of claims in 2018, we estimate that Part D would need a manufacturer discount rate in the catastrophic phase of about 15 percent—applied to prescriptions filled by beneficiaries both with and without the LIS—to ensure that the aggregate amount paid by manufacturers would be as large as the amount that would be paid under the current coverage-gap discount program. That estimate is for one year (2018) and does not incorporate any behavioral assumptions about how beneficiaries, plan sponsors, and manufacturers might respond to a discount in the catastrophic phase. The estimate also does not reflect any changes in the distribution of Part D spending in later years as new products entered the market.

Alternatively, a discount in the catastrophic phase could be set at a higher rate to offset other costs of the restructured benefit. Policymakers could also choose to pay for the restructured benefit through higher enrollee premiums, higher Medicare program spending, or both. For example, we estimate that in 2018, a 20 percent discount rate would have been needed to replace the coverage-gap discount and cover the costs of a new OOP cap. An estimated 35 percent rate would have been needed to cover both of those policy changes as well as the costs of eliminating the coverage gap for LIS enrollees. However, it is worth emphasizing that those figures are based on a snapshot of 2018 spending. In future years, as more high-priced drugs enter the market, the share of Part D spending made up of catastrophic benefits is likely to grow. In turn, a discount in the catastrophic phase would cover a larger share of Part D spending, offsetting more of the costs of the expanded benefits. Reflected in the recommendations presented later in this chapter, the Commission chose a manufacturer discount rate of at least 30 percent to include manufacturers among the stakeholders that would bear strong direct effects of drug price increases. A 30 percent discount would also help offset what would otherwise be increases in enrollee premiums and Medicare program spending resulting from Part D's new benefit structure.

Lower Medicare's individual reinsurance and increase plan liability

Part D's individual reinsurance is one component of a system of risk-sharing mechanisms. Before the start of Part D, stand-alone PDPs did not exist. Policymakers initially included Medicare's reinsurance and risk corridors

to encourage plan sponsors to enter this new market and compete. In 2015, the Commission reviewed Part D's tools for sharing risk—reinsurance, risk adjustment, and risk corridors—and discussed whether all three were still necessary in what had by then become an established market (Medicare Payment Advisory Commission 2015).

Reinsurance is one mechanism to give plan sponsors protection against unpredictable variation in pharmacy spending. For commercial and employer health plans, private individual reinsurance (also called individual stop-loss protection) is designed to serve a very specific purpose: to offset the unpredictable financial risk of extremely high claims from a few members. Because most commercial health plans insure both medical and pharmacy benefits, reinsurance contracts written for those plans generally cover both types of spending.

The more generous structure of Medicare's reinsurance and the predictability of most spending covered by Part D reinsurance suggest that individual reinsurance is serving a different function than it does for commercial health plans (Medicare Payment Advisory Commission 2016). In commercial plans, reinsurance typically has a higher spending threshold and may cover only the top 1 percent or 2 percent of enrollees with the highest spending (Bachler et al. 2019, Medicare Payment Advisory Commission 2015). By comparison, Medicare pays reinsurance for about 8 percent of Part D enrollees. Private reinsurers of commercial plans may exclude individuals with predictably high spending from future reinsurance coverage. Rather than acting as a stop loss against unexpectedly high spending, Medicare's reinsurance has been providing targeted cost-based reimbursement for high-cost enrollees, whether spending for those individuals is predictable or not.

The Commission's new approach to restructuring Part D would lower Medicare's reinsurance from 80 percent to 20 percent of catastrophic spending and increase plan sponsors' financial risk for benefit spending. More of Medicare's overall subsidy would be paid through capitated payments, adjusted by risk scores that would be recalibrated to the higher level of plan liability. Those measures would give plan sponsors stronger incentives to manage benefits, which could improve their formulary design decisions. Medicare's overall subsidy would remain unchanged at about 74.5 percent of basic benefits, and the share of basic benefit costs paid by enrollees would remain at about 25.5 percent. Because of the sizable

nature of this shift in risk, policymakers could temporarily tighten Part D's risk corridors to protect plan sponsors and beneficiaries from unintended consequences. The Commission anticipates phasing in its recommendations over several years to give plan sponsors time to adjust to the new benefit structure. After the phase-in period, the Commission could revisit the issue of whether risk corridors are still needed.

A restructured Part D benefit

Table 5-4 (p. 136) compares a recommended restructured Part D benefit with the current defined standard benefit. The restructured benefit would eliminate the coverage-gap discount program that currently applies to enrollees without the LIS as well as the coverage gap for LIS enrollees. Those changes would create a standard benefit structure for all enrollees, and plans would become responsible for 75 percent of benefits between the deductible and the OOP threshold. The restructured benefit would have no beneficiary cost sharing in the catastrophic phase. Medicare's individual reinsurance would be lowered to 20 percent, with plan sponsors responsible for 80 percent of low-priced generics (below the specialty-tier dollar threshold) and 50 percent for all other drugs and biologics. The effects on stakeholders of restructuring Part D in this way would vary depending on the specific parameters chosen. Below, we highlight some key tradeoffs in setting those parameters and considerations for two types of Part D plans: those that serve LIS enrollees and employer group waiver plans.

Tradeoffs between a lower OOP threshold and benefit and premium costs

In 2022, Part D's OOP threshold is projected to be about \$7,100. Under that threshold, enrollees without the LIS who reach the threshold and take an average mix of brand-name and generic prescriptions would pay about \$3,100 themselves and brand manufacturers would provide about \$4,000 in coverage-gap discounts. If the coverage-gap discount program were eliminated, most individuals who now reach the catastrophic phase would not likely reach it as quickly, and some would not reach it at all.

Setting the OOP threshold at \$3,100 in 2022 would ensure that most enrollees reach the catastrophic phase with about the same amount of cost-sharing liability as under current law. If policymakers set the OOP threshold at a lower amount, it would provide greater financial protection for all enrollees. More beneficiaries would reach the

**TABLE
5-4**

The parameters of a restructured Part D benefit

	Current benefit	Restructured benefit
Transition period to the new catastrophic benefit	N/A	4 years
Benefit phases below OOP threshold:		
Enrollee cost sharing between deductible and ICL	25%	25%
Plan liability between deductible and ICL	75%	75%
Coverage gap between ICL and catastrophic phase?	Yes	No
Brand manufacturer discount	70% in coverage gap (prescriptions filled by enrollees without LIS)	None
Projected OOP threshold in 2022	\$3,100 (\$7,100)*	\$3,100
Total spending at OOP threshold	About \$11,000	About \$11,000
Distribution of catastrophic spending (above the OOP threshold):		
Beneficiary cost sharing	5%	0%
Medicare reinsurance	80%	20%
Plan liability	15%	80% for lower priced generics 50% for brands and high-priced generics
Manufacturer discount**	0%	30% for certain prescriptions filled by enrollees with and without LIS

Note: N/A (not applicable), OOP (out-of-pocket), ICL (initial coverage limit), LIS (low-income subsidy).
 *Under current law, in the coverage gap, both beneficiary spending and the 70 percent discount provided by brand manufacturers count toward the OOP threshold. In 2022, at the average mix of brand and generic spending, about \$3,100 of the \$7,100 threshold, would be paid by the beneficiary and \$4,000 would be covered by manufacturer discounts.
 **Would apply to brand-name drugs, biologics, biosimilars, and certain high-priced generic drugs.

Source: Illustrative parameters for MedPAC-recommended changes to Medicare's Part D benefit structure, 2020.

catastrophic phase of the benefit than under current law. However, because there would be no cost sharing in the catastrophic phase, Part D enrollees who reach the lower OOP threshold would likely use more medications relative to a higher OOP threshold, potentially increasing polypharmacy issues among some beneficiaries. That change, in turn, would tend to put upward pressure on Part D benefit costs and enrollee premiums.

Trade-offs of a higher manufacturer discount in the catastrophic phase

Striking the right balance between plan and manufacturer liability will be crucial in providing better plan incentives

while restraining high price growth. In the restructured benefit shown in Table 5-4, the catastrophic benefit would consist of lower Medicare reinsurance (20 percent), a new manufacturer discount (30 percent), and plan liability (50 percent for brand-name drugs, high-priced generics, and biologics and 80 percent for lower priced generic drugs). Increasing plan liability from the current 15 percent to a higher percentage is important in providing plan sponsors with stronger incentive to manage spending.

If policymakers were to select a manufacturer discount lower than 30 percent, plans would bear more insurance risk, which would provide them with stronger incentives to manage spending. Plans might also negotiate harder

for rebates but would still have limited ability to negotiate rebates for unique therapies. However, benefit costs and enrollee premiums would both be higher.

The Commission chose to recommend a manufacturer discount of at least 30 percent to discourage price increases and to help offset increases in benefit costs and enrollee premiums. Because the new manufacturer discount would apply more directly to high-priced products, it could be particularly useful for therapies in drug classes that have few or no competitors. Under a reform in which the discount rate in the catastrophic phase would increase proportionately with the average growth in catastrophic spending, manufacturers could be deterred from raising prices. However, the effectiveness of the discount at restraining price growth would vary across manufacturers and would depend on Medicare's share of each product's market. In addition, if a higher manufacturer discount further reduced plan sponsors' liability, on the margin, that could weaken plan incentives to manage spending. For that reason, if the discount were structured to increase beyond 30 percent commensurately with growth in average catastrophic prices, policymakers could consider reducing the share of catastrophic benefits paid through Medicare's reinsurance rather than reducing plans' share.

Considerations for plans serving low-income beneficiaries

In 2017, LIS enrollees made up 71 percent of beneficiaries with spending high enough to reach Part D's catastrophic phase. Most LIS beneficiaries are in plans that serve large numbers of LIS enrollees, including basic stand-alone PDPs and a type of specialized MA plan known as a dual-eligible special needs plan (D-SNP). The Commission's recommended Part D reforms would require plans to bear more financial risk by expanding the use of capitated payments and reducing the use of cost-based payments for the LICs and reinsurance. To ensure stability in plan options for LIS beneficiaries, policymakers would need to phase in the new structure of Medicare's subsidies over several years. New tools would help plan sponsors better manage drug spending for LIS enrollees, and CMS would need to recalibrate the Part D risk adjustment system to reflect the higher plan liability.

A significant number of Part D plans serve primarily LIS enrollees LIS enrollment varies across plans, largely due to deliberate policy choices in both the Part D and MA programs. Medicare encourages LIS beneficiaries to enroll in basic PDPs by setting the maximum amount

the program will pay for low-income premium subsidies at regional benchmarks calculated from plans' premiums for basic coverage. In 2019, of the 7.3 million LIS beneficiaries enrolled in stand-alone PDPs, more than 90 percent were in plans that offered basic coverage. In that year, LIS beneficiaries accounted for 55 percent of enrollees in basic PDPs. Of the LIS beneficiaries in PDPs, 95 percent were enrolled in PDPs offered by five large companies—CVS Health, UnitedHealth Group, Humana, WellCare (recently purchased by Centene), and Cigna (including its subsidiary Express Scripts).

Of the 5 million LIS beneficiaries enrolled in MA-PDs in 2019, just over half (2.5 million people) were in traditional plans and another 45 percent (2.2 million people) were in D-SNPs.⁶ Traditional MA-PDs are open to all beneficiaries in a plan's service area, but special needs plans are limited to certain types of beneficiaries, with D-SNPs serving dual eligibles. As a result, LIS beneficiaries account for a relatively small share of enrollment in traditional MA-PDs (18 percent) but account for virtually all D-SNP enrollment.⁷ LIS enrollment in MA-PDs is less concentrated among a few major companies than is LIS enrollment in PDPs. In addition to large, vertically integrated health plans, MA plan sponsors include a broader variety of companies such as smaller regional organizations, religious-affiliated groups, and integrated delivery systems. However, most sponsors of smaller MA-PDs contract with large pharmacy benefit managers (PBMs) to provide outpatient drug benefits and negotiate postsale rebates and discounts with drug manufacturers and pharmacies.⁸

In 2019, there were 1,021 Part D plans in which LIS beneficiaries made up the majority of each plan's enrollees (Table 5-5, p. 138). (Those majority-LIS plans made up about one-quarter of all Part D plans in 2019 (data not shown).) Those plans covered about two-thirds of the LIS population (8.2 million out of 12.7 million), with most individuals enrolled in basic PDPs and D-SNPs.

Monitor effects of restructuring on MA-PDs that serve mostly LIS enrollees The reforms would result in higher capitated payments (consisting of Medicare's direct subsidy payments to plans and premiums paid by enrollees and by Medicare for LIS enrollees) for all enrollees, but the impact for LIS beneficiaries would be larger. Table 5-6 (p. 139) shows how 2017 spending was financed for beneficiaries with and without the LIS and demonstrates how the role of each funding stream would change under the Commission's recommended reforms.

**TABLE
5-5**

A significant number of Part D plans served primarily LIS beneficiaries, 2019

	Plans	Enrollees (in thousands)		Average share of enrollees	
		With LIS	Without LIS	With LIS	Without LIS
Plans with majority-LIS enrollment					
Basic PDPs	187	5,124	2,387	68%	32%
Traditional MA-PDs	150	334	80	81	19
C-SNPs	14	49	4	92	8
D-SNPs	413	2,238	8	100	<1
I-SNPs	81	78	4	95	5
MMPs	50	380	1	100	<1
PACE	126	43	1	99	1
Total	1,021	8,246	2,485	77	23

Note: LIS (low-income subsidy), PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]), C-SNP (chronic condition special needs plan), D-SNP (dual-eligible special needs plan), I-SNP (institutional special needs plan), MMP (Medicare-Medicaid Plan), PACE (Program of All-Inclusive Care for the Elderly). Figures based on Part D enrollment data for April 2019. Does not include plans in the U.S. territories.

Source: MedPAC analysis of CMS Part D enrollment data.

Under this reform package, Medicare’s capitated payments to plans would account for a substantially larger share of total spending, rising from 28 percent to 58 percent for LIS beneficiaries and from 40 percent to 60 percent for the other Part D beneficiaries. The share of spending financed by Medicare’s reinsurance and the LIS would decline, but it is worth noting that they and the other types of funding would still account for about 40 percent of total spending.

In dollar terms, the recommended reforms would lead to higher capitated payments for both kinds of beneficiaries, but the increase for LIS beneficiaries would be larger. The average monthly capitated payment for LIS beneficiaries would more than double, rising from \$139 to \$289, while the average payment for Part D beneficiaries without the LIS would rise from \$87 to \$130. The increase for LIS beneficiaries, \$150, would be larger because these beneficiaries have higher gross spending, on average, than Part D beneficiaries without the LIS and because the majority of that spending is currently financed through Medicare’s reinsurance and the LICS (40 percent and 31 percent, respectively). In contrast, Medicare’s reinsurance payments for beneficiaries without the LIS account for 23 percent of gross drug spending. Under the recommended reform package, Medicare’s payments for reinsurance and

the LICS would be lower but would be mostly offset by higher capitated payments. As a result, capitated payments for LIS beneficiaries would be an average of 2.2 times higher than capitated payments for Part D beneficiaries without the LIS (compared with 1.6 times higher under the current program).

Because of the differences between LIS and the other Part D beneficiaries, we interviewed several plan sponsors and actuaries with Part D plan expertise to learn about their experience with the LIS population. These sponsors consisted of a mix of large, for-profit companies that operate both stand-alone PDPs and MA-PDs and smaller, nonprofit companies that operate regional MA-PDs. Each sponsor had at least one plan, such as a basic PDP or D-SNP, in which most of the enrollees were LIS beneficiaries. Although interviewees were not drawn from a representative sample of all majority-LIS plans, their comments helped to highlight issues that policymakers could consider related to restructuring Part D.

There was broad agreement among interviewees that Part D reforms should be phased in to give plans time to adjust to the added financial risk and to avoid unnecessary disruptions. All interviewees emphasized

**TABLE
5-6**

An illustrative example of how the Commission’s recommended reforms would affect spending for LIS enrollees versus other Part D enrollees

	Average gross spending (per enrollee per month, 2017)			Distribution of gross spending	
	Actual	Under reformed benefit	Change	Actual	Under reformed benefit
LIS enrollees					
Total gross drug spending	\$502	\$502	\$0	100%	100%
Medicare reinsurance	202	50	-152	40	10
Capitated payments	139	289	150	28	58
LICS	155	81	-74	31	16
Manufacturer discounts in catastrophic phase	0	75	75	0	15
Out-of-pocket spending	6	6	0	1	1
Other Part D enrollees					
Total gross drug spending	\$218	\$218	\$0	100%	100
Medicare reinsurance	49	12	-37	23	6
Capitated payments	87	130	43	40	60
Manufacturer coverage-gap discounts	16	0	-16	7	0
Manufacturer discounts in catastrophic phase	0	18	18	0	8
Out-of-pocket spending	44	36	-8	20	17
Other	21	21	0	10	10
Ratio of LIS capitated payments to other Part D beneficiaries’ capitated payments	1.6	2.2			

Note: LIS (low-income subsidy), LICS (low-income cost-sharing subsidy). “Other Part D enrollees” refers to Part D enrollees without the LIS. “Gross spending” refers to amounts paid at the pharmacy before postsale rebates and discounts. The “under reformed benefit” columns show the combined effects of the following Part D reforms: eliminating the coverage gap for LIS enrollees, eliminating the coverage-gap discount program, adding an annual cap on beneficiary out-of-pocket costs, lowering the use of reinsurance in the catastrophic phase from 80 percent to 20 percent, requiring manufacturers of brand-name drugs to provide a discount of 30 percent on brand-name drugs and high-cost generic drugs used in the catastrophic phase, and increasing the share of catastrophic benefits financed by capitation payments from 15 percent to 50 percent for brands and generics and 80 percent for all other drugs. Capitated payments consist of Medicare’s direct subsidy payments to plans and premiums paid by enrollees and LIS for LIS enrollees. The “other” figures include payments by patient assistance organizations and third-party payers other than Part D plans that reduce beneficiary cost-sharing liability. Figures do not incorporate behavioral responses by plans and beneficiaries that would change total gross drug spending. Figures do not reflect the effects of postsale rebates and discounts and thus cannot be used to estimate the effect that the proposed reforms would have on Part D premiums. Components may not sum to totals because of rounding.

Source: MedPAC analysis based on average monthly spending amounts per enrollee with and without the LIS in 2017 Part D prescription drug event data.

that the Part D risk adjustment model would need to be recalibrated to ensure that payments for LIS beneficiaries remained adequate.

Interviewees distinguished between the new liability that plans would bear for what is now coverage-gap spending compared with higher plan liability in Part D’s catastrophic phase. Our interviewees did not believe that requiring plans to cover 75 percent of costs in the coverage gap would pose the same risk as the catastrophic benefit

costs because coverage-gap spending falls within a narrow range and is relatively predictable. However, interviewees expressed concern that payment rates for some high-cost beneficiaries might be too low. The primary concern was that even with higher capitated payments, reductions in Medicare’s reinsurance could lead to an increase in “high-cost outlier” cases in which risk-adjusted payments were substantially below actual costs. One interviewee said that Medicare should continue to use reinsurance to cover at

least some spending in the catastrophic phase because that would take some pressure off the risk adjustment system (i.e., CMS’s risk adjustment model would not need to predict spending for high-cost beneficiaries as accurately as it otherwise would).

Interviewees said that smaller plans, such as regional MA–PDs, would be more vulnerable to high-cost outliers, but when asked, they did not provide specifics on how a “smaller plan” might be defined. They noted that some plan sponsors might respond by purchasing private reinsurance to limit their potential exposure—although one sponsor said the profit markups on this coverage would make it prohibitively expensive—and said that policymakers could provide additional protection while the reforms were being implemented by modifying Part D’s risk corridors.

We also examined data on Part D’s risk corridor payments for 2015, the most recent available, to compare the performance of plans in which LIS beneficiaries made up the majority of enrollees with the performance of other plans. The risk-corridor data show how the actual costs that plans incurred to provide Part D benefits compared with the assumptions plans used in their bids. We found that bids for majority-LIS plans were about as accurate as bids for other plans, indicating that majority-LIS plans could accurately predict the costs for their enrollees and were not at greater risk of unexpected financial losses. In addition, majority-LIS plans typically did a better job of predicting how much of their enrollees’ drug spending would be covered by the LICS. Because the recommended reforms would take some spending that Medicare’s LICS now covers and make it part of the basic Part D benefit, these findings suggest that majority-LIS plans would be able to accurately account for the effects of those changes when they developed their bids.

Considerations for employer group waiver plans

Employer group waiver plans (EGWPs) are sponsored by employers that contract directly with CMS or on a group basis with an insurer or PBM to administer the Part D benefit. They differ from employer plans that receive Part D’s retiree drug subsidy (RDS) in that Medicare is the primary payer rather than the employer.⁹ Under accounting standards, private employers and state and local governments are required to calculate and report their unfunded liabilities for future pensions and other postemployment retirement benefits such as for prescription drugs. By putting retirees into EGWPs that benefit from both Medicare’s general Part D subsidy

as well as manufacturer discounts in the coverage gap, employers substantially reduce the magnitude of their unfunded liability.

EGWPs have distinct characteristics from other Part D plans. As a result, certain pieces of the recommended Part D reforms are likely to have a different impact on EGWPs than on other plans. One key difference is that EGWPs do not submit bids. Instead, Medicare pays EGWPs based on the national average of bids from nonemployer Part D plans. Another difference is that EGWPs are not eligible for risk-corridor payments. Under the restructured benefit, plan bids would increase to reflect their higher liability for benefit costs in the coverage gap and the catastrophic phase. In turn, Medicare’s direct subsidy payments to EGWPs would also increase.

EGWPs receive a disproportionate share of coverage-gap discounts: In 2018, EGWPs had 16 percent of Part D enrollees but received 45 percent of coverage-gap discounts (Medicare Payment Advisory Commission 2020b). EGWPs received more discounts because they tend to offer more generous benefits that supplement the standard Part D benefit. Under Part D’s “true out-of-pocket” provision, those supplemental benefits do not count as an enrollee’s OOP costs. As a result, EGWP enrollees who reach the coverage gap tend to stay there longer than enrollees without supplemental coverage. EGWPs also receive more discounts because they have very few LIS enrollees and thus a higher share of enrollees eligible for the discounts. In 2018, 98 percent of enrollees in EGWPs were eligible for coverage-gap discounts because they did not receive the LIS, compared with the roughly two-thirds of enrollees in other Part D plans. As a result, eliminating the coverage-gap discount under the reform would likely have a larger financial impact on EGWPs than on other Part D plans.

Under the reformed benefit, there would be a new manufacturer discount in the catastrophic phase that would apply to all enrollees. However, if EGWPs continued to provide supplemental benefits that prevented or delayed enrollees from reaching the catastrophic phase of the benefit, EGWPs would receive fewer manufacturer discounts than they do now. At the same time, because CMS would need to go through the rule-making process to implement the restructured benefit, we expect employers would have time to adjust their benefit offerings or switch to providing the prescription drug benefit through an RDS-eligible plan before facing the full financial impact of the reform.

Other modifications to Part D associated with a restructured benefit

The Commission believes that a Part D reform package that requires plan sponsors to assume greater financial risk should include complementary reforms to provide plan sponsors with greater flexibility to manage drug spending. In its June 2016 recommendations, the Commission included modifying the LIS to encourage greater use of lower cost drugs, removing protected status from two of the six drug classes for which plan sponsors must now cover all drugs on their formularies, 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.¹⁰ Part D's risk adjustment system would be recalibrated, and risk corridors could be modified as well.

Part D plan sponsors use formulary tools to manage benefits, but are subject to more constraints than commercial plans

The universe of drugs that Part D plans can cover generally includes, with a limited number of exceptions, any outpatient prescription agent approved by the Food and Drug Administration whose manufacturer has signed a contract with CMS to provide statutory rebates in the Medicaid program.¹¹ From that range of products, the pharmacy and therapeutics committee of each Part D plan sponsor selects specific drugs and biologics to include on its formulary. Those selections are based on considerations about therapeutic effectiveness as well as the relative price of competing products, net of any rebates and discounts negotiated with manufacturers and pharmacies. To make sure that each plan's formulary design does not substantially discourage enrollment by certain eligible individuals, CMS reviews plan formularies to check that they include medicines in a wide range of therapeutic classes used by the Medicare population. For most drug classes, plans must cover at least two chemically distinct drugs, as well as "all or substantially all drugs" in six protected classes—anticonvulsants, antidepressants, antipsychotics, immunosuppressants, antiretrovirals, and antineoplastics.

Sponsors manage the Part D benefit using the same strategies they employ for commercial clients: designing tiered formularies with differential cost sharing to encourage use of lower cost drugs, which gives sponsors leverage in negotiations with drug manufacturers for rebates. Plan sponsors may use utilization management

tools such as prior authorization and step therapy to encourage enrollees to use generics and preferred drugs or to help ensure patient safety. In general, plan sponsors would have the greatest leverage for price concessions when they can credibly threaten not to cover a drug on their formularies. However, sponsors are subject to more regulatory oversight in Part D than in the commercial sector, and CMS must approve each plan's formulary and utilization management requirements. Some Part D regulations, such as the protected-class policy, expand beneficiaries' access to drug therapies but can also reduce plan sponsors' negotiating leverage with manufacturers. The policy likely contributes to the high prices of some drugs in the protected classes (Centers for Medicare & Medicaid Services 2018b, Kocot et al. 2019).

Medicare also requires plan sponsors to establish a process for coverage determination and appeals. There are limits as to what available data can tell us about how well Part D's exceptions and appeals processes work. Nevertheless, CMS data show that in 2017, 3.5 percent of Part D transactions were rejected at the pharmacy because the drug was not on the plan's formulary or because of plan requirements for prior authorization, quantity limits, or step therapy (Office of Inspector General 2019). Of those reported rejections, about 10 percent proceeded to a plan coverage determination, and more than 70 percent of those claims were ultimately approved in favor of the patient by either the plan itself or by an independent review entity.

A more constructive approach toward ensuring appropriate access would be to provide enrollees and prescribers with real-time information about formulary coverage and utilization management requirements. (See text box on resolving coverage issues at the point of prescribing, p. 142.) These tools could reduce the need for appeals and increase the likelihood that beneficiaries receive an appropriate medicine in a timely manner. If built into the prescriber's workflow, standardized approaches to real-time benefit check, electronic prior authorization, and automated coverage determinations could also save patients and providers significant time and resources and speed up delivery of care (American Medical Association–convened workgroup of 17 state and specialty medical societies 2019).

Part D's low-income cost-sharing subsidy limits out-of-pocket costs, but also reduces incentives to use lower cost drugs

The cost-sharing subsidy sharply reduces OOP costs for LIS beneficiaries. Medicare pays for the deductible and

Resolving coverage issues at the point of prescribing

Rather than relying on the exceptions and appeals process, a better approach to resolving questions about coverage would be to use electronic tools such as real-time benefit tools (RTBTs) and electronic prior authorization (ePA).

For several years, health plans and pharmacy benefit managers (PBMs) have operated portals that prescribers could use to look up formulary and benefit (F&B) information. However, portals can be time consuming because they fall outside the regular workflow of prescribers, and providers typically need to navigate several portals for information across their patient panel. Part D plan sponsors currently are required to disseminate F&B information on a nightly, weekly, or monthly schedule, but that approach does not provide patient-specific data. Even when available, physicians may ignore F&B information because they have experienced inaccuracies or because it is displayed in a confusing manner. Physicians in one recent roundtable said they would like to know the approximate cost-sharing amount their patients would pay for various medicines rather than just formulary status and cost-sharing tier (BenMedica 2019). In addition, beneficiaries would also like to know the drug's cash price (to decide whether to use their plan benefit) as well as the availability of cost-sharing assistance (CoverMyMeds 2020).

By comparison, RTBTs operate as a module within a patient's electronic health record (EHR). RTBT technology allows the prescriber to see patient-specific details about benefits—such as whether a drug is covered on a formulary, alternative drugs that are covered, prior authorization requirements, total drug cost, beneficiary cost sharing, and pharmacy network status—before ordering a prescription. ePA tools allow the prescriber to submit a request to the patient's plan in real time and, for automated plan reviews, potentially receive approval much more quickly than manual plan reviews. After receiving an ePA approval, the prescriber

orders the prescription and sends it to the desired pharmacy for dispensing.

Part D plan sponsors have long been required to support electronic prescribing, which in 2018 was used by approximately 73 percent of prescribers and 99 percent of pharmacies (SureScripts 2018). In 2019, CMS finalized a rule (CMS-4180-F) requiring Part D sponsors to implement one or more RTBTs capable of integrating with at least one prescriber's EHR system by January 1, 2021. However, the extent to which this requirement increases the use of RTBTs in Part D will depend on the degree to which clinicians—who face no requirements under this rule—adopt them when prescribing for their Medicare patients.

Although many EHR vendors, payers, and PBMs already support RTBTs and ePA, phone and fax continue to be the most common ways of completing prior authorization (American Medical Association 2019, CoverMyMeds 2020). One key reason is that the electronic tools do not communicate with all relevant PBMs. For example, SureScripts, which is partly owned by CVS Health and Express Scripts, does not include RTBT data from OptumRx, which is owned by UnitedHealthcare, while OptumRx's tool does not support CVS Health or Express Scripts (Galewitz 2019). There are no industry-wide electronic standards for using the electronic tools, and certain proprietary features of EHRs prevent systems from communicating with one another.

Perhaps the most essential requirement for adoption of electronic tools is clinician acceptance and use, which can require paying fees to vendors and embracing practice pattern change. Some prescribers may not be aware of the tools. According to one recent survey, only 21 percent of physicians reported that they knew their EHR system offered ePA (American Medical Association 2019). In addition, some prescribers require demonstration that the tools could lead to efficiencies rather than contribute to greater workload. ■

coverage gap for most LIS enrollees, and Part D law also sets maximum amounts that LIS beneficiaries pay for each prescription, which cannot be modified by CMS or plan sponsors. In 2017, LIS enrollees paid, on average, \$6 per

month out of pocket, or about 1 percent of their average gross drug spending of \$502 per month. By comparison, all other enrollees paid an average of \$44 per month out of pocket, or about 20 percent of their average gross

**TABLE
5-7**

LIS beneficiaries have weaker incentives to use lower cost drugs

Cost sharing in 2020

Formulary tier	Drug category	Median for stand-alone Part D plans	Maximum for LIS beneficiaries
Tier 1	Preferred generic drugs	\$0 copayment	\$3.60 copayment or less for most beneficiaries
Tier 2	Other generic drugs	\$3 copayment	
Tier 3	Preferred brand-name drugs	\$42 copayment	\$8.95 copayment or less for most beneficiaries
Tier 4	Nonpreferred drugs	38% coinsurance	
Tier 5	Specialty drugs	25% coinsurance	

Note: LIS (low-income subsidy). Some stand-alone Part D plans use copayments for drugs on Tier 3 while others use coinsurance; roughly 75 percent of enrollees are in plans that use copayments. The maximum cost sharing for an individual LIS beneficiary depends on several factors in addition to the drug’s brand/generic status, such as whether the beneficiary receives Medicaid-funded long-term services and supports and whether the beneficiary has reached Part D’s out-of-pocket threshold for catastrophic coverage.

Source: Centers for Medicare & Medicaid Services 2019a, Cubanski and Damico 2019.

spending of \$218 per month (Medicare Payment Advisory Commission 2019b).

Although the LIS helps ensure access to medicines, its limits on cost sharing also give LIS enrollees weaker incentives to use lower cost drugs and make it more difficult for plan sponsors to manage enrollees’ drug spending. For enrollees without the LIS, plan sponsors set cost-sharing requirements with strong incentives to select lower cost drugs (Table 5-7). For example, in 2020, the median copayment in stand-alone PDPs is \$0 for preferred generics and \$3 for other generics, compared with a median copayment of \$42 for preferred brand-name drugs (Cubanski and Damico 2019). Cost sharing was higher still for nonpreferred drug tiers and specialty tiers.¹² For the cost-sharing structure shown in Table 5-7, the savings to an LIS enrollee from taking a generic over a brand-name drug would be just over \$5 (\$8.95 minus \$3.60), but for the other Part D enrollees, the savings would be on average \$39 (\$42 minus \$3). Likewise, LIS enrollees have no incentive to use a plan’s preferred brand-name drug rather than other brand-name drugs because they would pay \$8.95 regardless.

Plan sponsors we interviewed indicated that managing spending and prescription use of LIS enrollees was more difficult than for other enrollees. In their view, the differential between copayments for generic and brand-

name drugs (about \$5) did not provide enough financial incentive for beneficiaries to use generics. Likewise, charging the same copayment for all brand-name drugs gave beneficiaries no incentive to use lower cost brands. Interviewees also noted that a number of LIS enrollees seek nonformulary exceptions for brand-name drugs that have generic equivalents, requiring the plan to cover a product not normally included on its formulary. Large numbers of nonformulary exceptions tend to undermine plan sponsors’ bargaining leverage in their negotiations with manufacturers for rebates. Nonformulary exceptions may be clinically warranted in some cases. However, for enrollees without the LIS who seek such an exception, they typically must pay the cost sharing of their plan’s nonpreferred tier.

Interviewees also reported that managing drug spending for LIS beneficiaries was more difficult because these enrollees were more likely to use drugs in Part D’s protected classes. Medicare’s requirement that plans cover “all or substantially all” drugs in the six classes ensures that beneficiaries who have conditions for which drugs play a key role in treatment have broad access to coverage. However, because manufacturers know that their products cannot be excluded from plan formularies, the policy also limits plan sponsors’ ability to obtain rebates on brand-name drugs. One recent study found that manufacturers provided rebates on fewer brand-name drugs in the

protected classes (13 percent vs. 36 percent of all brand-name drugs) and that the rebates they did provide were smaller (14 percent of gross costs vs. 30 percent for all brand-name drugs) (Johnson et al. 2018).

Claims data show that the generic dispensing rate (GDR)—the share of prescriptions filled with generic drugs—has consistently been lower for LIS enrollees. In 2017, LIS beneficiaries had a GDR about 5 percentage points lower than that for other enrollees (85 percent vs. 90 percent). A representative of one sponsor we interviewed noted that even though differences in GDRs may not seem large, brand-name drugs are many times more expensive than most generics, and so lower use of generics by LIS beneficiaries has a material impact on plan costs. Lower generic use may partly reflect clinical differences, such as having a condition for which all available therapies are brand-name drugs. Nevertheless, regarding therapeutic classes for which all or most drugs have lost patent protection, claims data show that LIS enrollees are less likely to use generics. For example, in 2017, LIS beneficiaries had lower GDRs than other beneficiaries for proton pump inhibitors (88 percent vs. 97 percent), statins (96 percent vs. 99 percent), and certain antidepressants (92 percent vs. 98 percent). These differences suggest that clinical factors alone cannot fully explain lower generic use among LIS beneficiaries.

Greater flexibility in formulary management

Formulary design is the key tool used by plan sponsors to manage drug benefits and affect sponsors' bargaining leverage with pharmaceutical manufacturers. 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. In addition, the Secretary could consider other regulatory changes that would provide plan sponsors with more flexibility while maintaining beneficiary access to clinically appropriate medications.¹³

Allow plans to use a nonpreferred tier for specialty drugs

Under CMS's current guidance, plan sponsors may place drugs that cost \$670 per month or more on a specialty tier.¹⁴ Between 2007 and 2017, spending for specialty-tier drugs grew more than 10-fold—from \$3.4 billion to \$37.1 billion (Medicare Payment Advisory Commission 2019d). Spending for specialty-tier prescriptions made up nearly a quarter of gross Part D spending by 2017 (up from

5.5 percent in 2007), and likely an even larger share of spending after accounting for rebates and discounts.¹⁵

Some commercial plans have two specialty tiers (preferred and nonpreferred) to manage the use of specialty drugs. Such a tier structure could, if appropriately used, enhance patient care by providing access to specialty drugs while reducing inappropriate use. This tier structure could also encourage competition among existing specialty drugs that are therapeutic substitutes and could help encourage beneficiaries to consider using biosimilar products when they become available. Because more expensive or less clinically effective therapies could be placed on the nonpreferred tier, rather than be excluded from the formulary, this tier structure could reduce the need for nonformulary exceptions.

In February 2020, CMS proposed a policy to allow a second, "preferred" specialty tier in Part D with a lower cost-sharing amount (CMS-4190-P). CMS designed the proposal to give plan sponsors more tools to manage the drug benefit, and the Commission shares that goal. Nevertheless, the Commission noted in its comment letter that CMS's proposal may constrain plan sponsors in their design of new specialty tiers and keep them from being as effective as they could be (Medicare Payment Advisory Commission 2020a). The Commission encourages CMS to provide sponsors with greater flexibility to ensure they have meaningful tools to manage specialty-drug spending and leverage to negotiate rebates with manufacturers.

Differentiate LIS cost sharing for preferred and nonpreferred drugs

Plan sponsors, both in Part D and in the commercial market, routinely use differential cost sharing to make generics and lower cost drugs and biologics more attractive to enrollees. However, current LIS copayments provide much weaker financial incentives than those faced by other enrollees. If plan sponsors are to take on more risk for LIS enrollees, additional tools would help them better manage spending for this population.

In 2016, the Commission recommended that the Congress change Part D to modify LIS copayments to encourage the use of lower cost therapies in selected therapeutic classes (Medicare Payment Advisory Commission 2016). Those modifications could take the form of both decreases in cost sharing (e.g., zero copayments for preferred generics) and modest increases for certain nonpreferred prescriptions. To protect beneficiaries, under the recommendation, the Secretary would have authority to select therapeutic

**TABLE
5-8**

Illustrative example of requiring LIS beneficiaries to pay higher cost sharing for certain drugs

Drug category	Beneficiaries without the LIS	LIS beneficiaries	
		Current cost-sharing limit	Cost-sharing limit under policy
Generic	\$0 copayment	\$3.60*	
Other generic	\$3 copayment	\$3.60	No change*
Preferred drug (largely brands)	\$42 copayment	\$8.95	
Preferred specialty	15% coinsurance	\$8.95	
Nonpreferred drug (largely brands)	38% coinsurance	\$8.95	Modestly higher limits would apply*
Nonpreferred specialty	35% coinsurance	\$8.95	

Note: LIS (low-income subsidy).

*If the plan's standard cost-sharing amount is lower than the limit, LIS beneficiaries pay the standard amount. For example, under current law, the actual amount that LIS beneficiaries pay for drugs on the generic tier would be \$0.

Source: Cubanski and Damico 2019; CMS Office of the Actuary.

classes to which this policy would apply—classes that have generics or biosimilars available and for which substitution would be clinically appropriate.

Consistent with the 2016 recommendation, policymakers could consider allowing modestly higher cost sharing if an LIS beneficiary chooses to fill a prescription for a nonpreferred drug rather than an alternative on a preferred drug tier. (See text box on how low-income beneficiaries respond to cost sharing, pp. 146–147.) As is the case for the other Part D beneficiaries who seek a nonformulary exception, LIS beneficiaries who do so would pay the LIS copayment amount for nonpreferred tiers. Policymakers could also apply differential cost sharing to high-cost specialty drugs by allowing Part D plans to have separate preferred and nonpreferred tiers for specialty drugs. Plan formularies thus could have up to six tiers since there effectively could be two generic tiers as well as separate preferred and nonpreferred tiers for brand-name drugs and specialty drugs. The current LIS limits on cost sharing could still apply to the generic tiers and the preferred tiers; since plans must include at least one drug in each therapeutic class on a preferred tier, this policy would help ensure that LIS beneficiaries still had good access to coverage. Under this policy to include a new statutory LIS copayment amount for nonpreferred drugs and nonformulary exceptions, plans would make LIS enrollees

and their prescribers aware of preferred and nonpreferred therapeutic options for the patient as well as the relevant LIS copayment amounts.

Table 5-8 provides an illustrative example of how differential cost sharing could work for LIS beneficiaries. In this example, which focuses on LIS beneficiaries who currently pay \$3.60 for generics (the maximum copayment for drugs on the two generic tiers) and \$8.95 for brands, the preferred drug tier (which is largely brands) and the preferred specialty tier would remain the same, but the limits for the nonpreferred drug tier (again, largely brands) and the nonpreferred specialty tier would increase somewhat. However, differential cost sharing would not apply to those LIS beneficiaries who pay no cost sharing.¹⁶

Give plans greater flexibility in the protected drug classes

Medicare's requirement that plans cover all drugs in the six protected classes makes it harder for plans to obtain rebates and manage drug spending. Several sponsors said that plans would have an easier time managing drug costs for LIS beneficiaries if some of the restrictions on the protected drug classes were modified. For example, one sponsor said that most drugs in some protected classes have lost their patent protection and that many enrollees can now be effectively treated with generics. However, the

How low-income beneficiaries respond to cost sharing on prescription drugs

Researchers have consistently found that cost sharing reduces overall spending on prescription drugs, with one review of the literature concluding that a 10 percent increase in cost sharing reduces overall prescription drug spending by between 2 percent and 6 percent. Some studies have found that the sensitivity to cost sharing depends on the drug and that higher cost sharing has a smaller effect on the use of more essential drugs, such as those for chronic conditions. Research has also generally found that, for people with chronic conditions such as diabetes or schizophrenia, higher cost sharing for prescription drugs is associated with higher medical costs for services like inpatient care and emergency care. Although there is a widespread belief that low-income populations may be more sensitive to changes in cost sharing, “there is little reliable evidence to support this contention” (Goldman et al. 2007).

Most of the research on the effects of prescription drug cost sharing on low-income groups has looked at the experience in Medicaid (Goldman et al. 2007).

States can charge nominal copayments of up to \$4 for preferred drugs and \$8 for nonpreferred drugs (Medicaid and CHIP Payment and Access Commission 2018). As of 2018, 35 states and the District of Columbia have copayments for prescription drugs, usually ranging between \$0.50 and \$3 per prescription (Kaiser Family Foundation 2018). Research on the introduction of state copayments has found that even modest copayments can significantly affect prescription drug spending (Goldman et al. 2007). One study of Oregon’s Medicaid program found that the introduction of drug copayments did not lead to greater use of inpatient care or emergency care, even among individuals with chronic conditions (Hartung et al. 2008).

Two more-recent studies focusing on low-income populations examined the effects of modifying cost sharing for a subset of drugs, instead of applying cost sharing across all drugs. This targeted approach is more analogous to increasing cost sharing for nonpreferred drugs only. Both studies are somewhat cautionary tales.

(continued next page)

sponsor said that the potential savings from these generics have not been fully realized because the sponsor has had to cover several brand-name drugs that are new formulations of older medications but are not, in its view, any more effective.

The “protected class” policy was intended to ensure that beneficiaries who were transitioning from other drug coverage (e.g., Medicaid) to the Part D program would have uninterrupted access to medications in six classes. Currently, plan sponsors may apply utilization management to protected-class drugs and place therapeutic alternatives in protected classes on different cost-sharing tiers. However, because LIS cost-sharing amounts are set by law rather than by plans, the LIS enrollee does not face the same incentives to use the preferred product as other plan enrollees. More generally, the requirement to cover “all or substantially all” drugs in protected classes reduces plan sponsors’ bargaining leverage with manufacturers;

rebates are less easily obtained and are smaller, on average, for brand-name drugs in protected classes (Johnson et al. 2018). If LIS cost sharing were modified to allow differential copayments between preferred and nonpreferred drugs, plan sponsors would have more bargaining leverage with manufacturers for rebates.

The Commission has previously expressed support for giving plans greater flexibility with the protected classes. In 2016, we recommended removing antidepressants and immunosuppressants from the protected classes (Medicare Payment Advisory Commission 2016). In 2019, we supported a CMS proposal that would make it easier for plans to use formulary management tools in the protected classes (Medicare Payment Advisory Commission 2019a).¹⁷ The proposal would have allowed plan sponsors to use formulary tools more broadly under specific circumstances (e.g., use prior authorization to determine whether a drug was prescribed for a protected-

How low-income beneficiaries respond to cost sharing on prescription drugs (cont.)

The first study looked at changes to the copayments for prescription drugs in the Massachusetts Medicaid program (Lieberman et al. 2014). The state initially charged \$1 for generics and \$3 for brands. The state then raised the copayment for most generics from \$1 to \$3 but kept the \$1 copayment for certain targeted drug classes (antihypertensives, antihyperlipidemics, and hypoglycemics). The copayment for brand-name drugs did not change. The study found that, within the targeted drug classes, use of generic drugs increased while use of brands stayed the same. Higher generic usage was due to higher overall use in the targeted drug classes, rather than individuals switching from brands to generics. More importantly, the study found that elsewhere in the program, use of brand-name drugs increased and generic use decreased because enrollees no longer had an incentive to use generics. These findings underscore that even modest changes to cost sharing can affect patterns of prescription use. Policies to encourage Part D's low-income subsidy (LIS) beneficiaries to use preferred drugs over nonpreferred

ones—largely aimed at reallocating use among brand drugs—should be careful to preserve the basic incentive to use generics instead of brands when possible.

The second study looked at the effects of eliminating copayments for generics, a popular strategy for promoting the use of generics over expensive brand medications (Stuart et al. 2017). The study was unusual for two reasons: (1) It looked specifically at Part D enrollees who received the LIS (researchers typically exclude these beneficiaries from studies on the effects of differential cost sharing since the LIS covers most of their cost sharing), and (2) the treatment and control groups were randomly assigned. The study examined LIS beneficiaries who were assigned to new Part D plans and compared those placed in plans that had free generics in two drug classes (oral antidiabetic drugs and statins) with those placed in plans that had copayments. The study did not find any significant differences in generic utilization between the two groups, suggesting that eliminating copayments on generic drugs may have relatively little effect on the LIS population. ■

class indication) while maintaining appropriate access to all or substantially all drugs in protected classes (Centers for Medicare & Medicaid Services 2019b, Kocot et al. 2019). However, due to concerns raised by stakeholders, CMS chose not to finalize its proposal.

The importance of adequate risk adjustment

Risk adjustment plays a vital role in a capitated payment system by counterbalancing plan incentives for selection and ensuring that plans receive adequate payment for covering high-cost individuals, such as Part D's LIS beneficiaries. Since capitated payments would play a larger role in a redesigned Part D benefit, ensuring that payments are properly risk adjusted is a key concern for policymakers.

It would be critically important for CMS to recalibrate the prescription drug hierarchical condition category (RxHCC) model if policymakers expanded the amount

of Part D drug spending covered by capitated payments. (See text box on Part D risk adjustment, pp. 148–149.) CMS has periodically recalibrated the model to account for the effects of the Affordable Care Act of 2010, which gradually required Part D plans to cover some drug spending in the coverage gap for beneficiaries without the LIS. These revisions appear to have been successful in ensuring that payment rates for those beneficiaries remain sufficient. The transition to the new benefit structure may increase CMS's administrative burden by requiring it to recalibrate the model more frequently than it would normally. However, CMS has substantial experience with recalibration, both for routine updates and in response to policy changes, and we believe that the agency would be able to recalibrate the model to ensure adequate payments to plans.

The structure of the RxHCC model should make it feasible for CMS to recalibrate the model to account

Would Part D's risk adjusters disadvantage plans that enroll a higher share of low-income subsidy beneficiaries?

In Part D, CMS uses the prescription drug hierarchical condition category (RxHCC) model to adjust payments to reflect the health status of each plan's enrollees. The RxHCC model assigns each demographic characteristic and medical diagnosis a weight that represents its expected impact on an enrollee's overall costs. Between 2006 and 2010, CMS applied an early version of the model that used the same risk adjusters for all Part D beneficiaries. In 2011, CMS began using a revised model that split beneficiaries into five groups: low-income subsidy (LIS) beneficiaries living in the community (divided into those under 65 and those 65 and older), beneficiaries without the LIS living in the community (divided into those under 65 and those 65 and older), and beneficiaries living in long-term care facilities. These groups have distinctive drug-spending profiles, so the revised model has a separate set of risk adjusters for each group. Under the revised model, the risk adjusters for LIS beneficiaries are generally larger than the adjusters for beneficiaries without the LIS, resulting in higher payments for LIS beneficiaries.¹⁸

Although LIS beneficiaries have higher drug costs and plan sponsors believe it is more difficult to manage their drug utilization, the sponsors and actuaries we interviewed all said that the revised RxHCC model had improved payment rates for LIS beneficiaries and that payments for this population are now generally adequate.

The recommended reforms would result in higher capitated payments for all enrollees, with a larger impact—in dollar terms—for LIS beneficiaries. However, given the structure of the RxHCC model, we contend that CMS would be able to recalibrate the model to ensure adequate *overall* payment rates for both sets of enrollees. One concern is that, because risk adjustment models tend to underpredict very high spending and overpredict very low spending, plans that enroll a relatively high share of high-cost beneficiaries could be disadvantaged.¹⁹ The Commission is particularly concerned about smaller plan sponsors that enroll a higher share of LIS beneficiaries.

To examine whether plan sponsors with a higher share of LIS beneficiaries are likely to be disadvantaged as a result of inadequate risk adjustment, we used 2018 claims data to compare variation in Part D's gross drug spending for LIS and other populations. We measured relative variation using the coefficient of variation (CV)—the standard deviation of individuals' annual spending divided by mean spending. A higher CV means there is more variation relative to the average. We found that although LIS enrollees have more than twice the average spending of enrollees without the LIS, relative variation in LIS spending is lower. In 2018, mean drug spending for LIS beneficiaries was \$6,371 compared with \$2,740 for other Part D beneficiaries (Table 5-9). However, the CV for LIS beneficiaries (280 percent) was considerably lower than for beneficiaries without the LIS (417 percent).

This difference in CVs reflects distinct patterns of prescription use and spending for these two populations. The majority of beneficiaries without the LIS used primarily low-cost generics and had relatively low spending. However, a relatively small share of these beneficiaries (3 percent in 2018) incurred spending high enough to reach the out-of-pocket (OOP) threshold. LIS beneficiaries, on the other hand, tended to have higher spending and were more likely to reach the OOP threshold: 19 percent did so in 2018.

To evaluate the potential effects of recalibration, it is useful to consider separately the two elements of higher liability that plans would incur under a restructured Part D benefit—more coverage-gap spending and catastrophic spending. We repeated our CV analysis on Part D claims but separately evaluated beneficiaries' spending below and above the OOP threshold. For LIS enrollees, average spending below the OOP threshold was \$3,037, and variation around that mean was relatively low: 99 percent (Table 5-9). By comparison, enrollees without the LIS had lower average spending below the threshold (\$1,909) but nearly twice as much relative variation around their mean (195 percent). This contrast suggests that as sponsors consider the additional liability that their plans would incur below

(continued next page)

Would Part D's risk adjusters disadvantage plans that enroll a higher share of low-income subsidy beneficiaries? (cont.)

the OOP threshold (including in the coverage gap), spending for LIS enrollees may be more predictable than spending for other enrollees. Likewise, as CMS recalibrates its risk adjusters for LIS enrollees, the agency's RxHCC model will have relatively less variation to explain below the OOP threshold than its models for other enrollees.

By comparison, catastrophic spending (spending above the OOP threshold) is less predictable than coverage-gap spending because the extreme values are influenced more heavily by use of high-priced drug and biologic treatments for less prevalent conditions, such as cancer and rheumatoid arthritis. For LIS enrollees (including those with no drug spending as well as individuals well above the OOP threshold), catastrophic spending averaged \$3,306 and varied widely (a CV of 506 percent) (Table 5-9). By comparison, average catastrophic spending for the other Part D enrollees was much lower (\$832). However, the relative variation

around that average was more than twice as large (1,169 percent). This suggests a recalibrated risk adjustment model is more likely to underpredict very high spending incurred by beneficiaries without the LIS than beneficiaries with the LIS.

In our analysis of claims data, we found that many LIS beneficiaries reach the catastrophic phase of the benefit using medications for chronic or more prevalent conditions (Medicare Payment Advisory Commission 2016). Beneficiaries without the LIS have more extreme spending than do LIS enrollees. In 2018, of the beneficiaries who reached the OOP threshold and did not receive the LIS, 10 percent incurred more than \$84,753 in gross Part D spending. Less than 5 percent of LIS beneficiaries who reached the OOP threshold reached that level of spending (data not shown), and the threshold for reaching the top 10 percent ranked by spending was \$44,780 (Table 5-9). ■

**TABLE
5-9**

Spending varied more for beneficiaries without the LIS than for LIS beneficiaries, 2018

	Beneficiaries without LIS		Beneficiaries with LIS	
	Mean	Coefficient of variation	Mean	Coefficient of variation
All Part D beneficiaries				
Annual spending per person	\$2,740	417%	\$6,371	280%
Spending below the OOP threshold	1,909	195%	3,037	99%
Spending above the OOP threshold	832	1,169%	3,306	506%
Distribution of spending for beneficiaries who reach the OOP threshold				
Mean	\$34,314		\$23,215	
Median	16,925		14,159	
90th percentile	84,753		44,780	

Note: LIS (low-income subsidy), OOP (out-of-pocket). Spending reflects prices paid at the pharmacy (gross spending) before postsale rebates and discounts. The coefficient of variation is the standard deviation of annual spending per person divided by the mean. Enrollees were included in this analysis if they were enrolled in Part D for the full benefit year. Values include enrollees who had no claims.

Source: MedPAC analysis of Part D's prescription drug event data.

for the disproportionate impact that the reform package would have on the average capitated payments for LIS beneficiaries. The key feature that makes this possible is the use of separate risk adjusters for LIS beneficiaries versus the other Part D beneficiaries. When CMS calculates these adjusters, it implicitly accounts for any differences in the average costs of the two populations. For example, under the illustrative example shown in Table 5-6 (p. 139), recalibrated risk adjusters would ensure that average capitated payments for LIS beneficiaries increased from \$139 to \$289, while payments for the other Part D beneficiaries would increase from \$87 to \$130.

However, it is important to note that the RxHCC model is not designed to predict costs for individual beneficiaries; it aims instead to predict costs for groups of beneficiaries, like the enrollees in a health plan. As a result, while we believe that the RxHCC model could be recalibrated to provide an adequate overall level of risk adjustment for plans that serve LIS beneficiaries, the recalibrated model might nonetheless underestimate costs for certain types of beneficiaries, such as those who use very high-cost drugs. These high-cost outliers might pose a greater risk for regional PDPs and MA-PDs because, compared with large plans offered by national sponsors (for which the effects of high-cost outliers are more likely to average out), they typically have lower enrollment and thus less ability to absorb losses. For example, some regional sponsors have little or no presence in other lines of business, such as commercial coverage or Medicaid managed care, that could be used to offset unexpected Part D losses, and regional sponsors that are nonprofit organizations may have lower capital reserves.

Because CMS estimates RxHCCs using past Part D claims, the model is not intended to adjust immediately for entries of new high-priced drugs. As a result, if those new entries are not anticipated by plan sponsors, and therefore are not reflected in their bids, plan sponsors could experience costs that exceed their risk-adjusted payments (and premiums). When new therapies for hepatitis C entered the market, CMS manually modified certain RxHCCs to reflect high-priced treatments until Part D claims data for the products became available to recalibrate the risk adjustment model.

While cases like hepatitis C drugs are not likely to occur frequently, CMS may want to investigate whether the RxHCC model could incorporate major therapeutic innovations more quickly to prevent large and systematic

underpayments or overpayments for a particular condition. At the same time, if Medicare were to base plan payments on risk-adjusted amounts that predict actual spending too closely, the result would differ little from using a system of cost-based reimbursement rather than one of prospective payment.

Transitional changes to risk corridors

The recommended reforms would require plan sponsors to bear more financial risk by expanding the use of capitated payments and reducing the use of cost-based payments for the LICs and reinsurance. We anticipate that, under a restructured Part D, some plans could experience spending patterns that are more variable than their historical experience based on the current plan liability.

Some stakeholders we interviewed suggest that drug spending is inherently more difficult to predict than medical spending because of uncertainties about when new drugs will enter the market, their launch prices, and the extent to which new therapies will be prescribed. Because high-priced orphan and specialty drugs have made up larger shares of new medications in the development pipeline, most interviewees thought that drug spending had grown more difficult to predict over time. In an earlier analysis, we found that between 2008 and 2012, variation in Medicare beneficiaries' drug spending had grown, but was roughly comparable with variation in medical spending by the end of the period (Medicare Payment Advisory Commission 2015). In an updated analysis, we found that variation in drug spending now exceeds that of FFS medical spending. However, variation was driven mostly by predictable spending; nearly 80 percent of spending in the catastrophic phase was attributable to beneficiaries who had catastrophic spending in the previous year, meaning that unexpected costs accounted for only about 20 percent of total catastrophic costs.

It would be very important for CMS to recalibrate the RxHCC model to ensure that plans are compensated appropriately and to discourage plan sponsors from engaging in risk selection. However, given the higher insurance risk associated with spending in the catastrophic phase of the benefit, the recalibration of the RxHCC model could be insufficient to achieve those goals, at least during a transition period. Further, plan sponsors with smaller membership size could be less able to absorb the effects of an unexpected change in the pharmaceutical market (e.g., the unanticipated launch of an expensive new medication) compared with their larger counterparts.

Part D's risk corridors limit (but do not cap) a plan's overall losses across all its enrollees when actual spending for basic benefits is higher than predicted spending. (Since Part D's risk corridors are symmetric, they also limit a plan's unanticipated profits.) In contrast to Medicare's individual reinsurance that protects plans against unexpectedly high costs incurred by individual enrollees, risk corridors provide a cushion at the plan level in the event of unforeseen high drug spending.

Currently, plan sponsors are at full financial risk if actual benefit spending is within the range of 95 percent to 105 percent of the plan's bid. (That is, a plan is fully at risk for spending up to 5 percent above its bid (losses) or 5 percent below (profits).) If actual benefit spending is either between 105 percent and 110 percent of the bid or between 90 percent and 95 percent of the bid, Medicare splits the difference with the plan sponsor between the bid and actual benefit spending 50–50. Beyond 110 percent or below 90 percent, Medicare covers 80 percent of excess benefit costs (or recoups excess profits).

If plan sponsors are to assume a greater share of spending in the catastrophic phase of the benefit, policymakers could consider making the risk corridors more generous to provide greater protection. For example, policymakers could narrow the risk corridors so that plans are fully at risk for less than 5 percent above or below their bids. Because plan bids would be higher with a restructured benefit than with the current benefit structure, a narrower corridor would help to keep the potential losses (or profits) at a level closer to what plans face today. Policymakers could also consider different risk-sharing percentages in the corridors, including greater aggregate stop-loss protection, which could be particularly valuable for smaller plans and plan sponsors that do not have the scale to self-reinsure.

Recommendations for a restructured Part D benefit

Three interrelated recommendations for restructuring Part D have evolved from the Commission's 2016 recommendations to provide a package of reforms. Under our first recommendation, the Congress would change the benefit's design to introduce an OOP cap for all Part D beneficiaries and would reallocate the financial risk of benefit spending among plan sponsors, pharmaceutical

manufacturers, and the Medicare program. In the second recommendation, the Congress would make concurrent changes that would give plan sponsors greater flexibility to manage formularies and would tighten Part D's risk corridors during a transition period to the new benefit design. Under the third recommendation, CMS would facilitate greater formulary flexibility and ensure that Part D's risk adjustment system compensates plans for the higher benefit liability required under the new benefit design.

RECOMMENDATION 5 - 1

The Congress should make the following changes to the Part D prescription drug benefit:

- **Below the out-of-pocket threshold:**
 - **Eliminate the initial coverage limit.**
 - **Eliminate the coverage-gap discount program.**
- **Above the out-of-pocket threshold:**
 - **Eliminate enrollee cost sharing.**
 - **Transition Medicare's reinsurance subsidy from 80 percent to 20 percent.**
 - **Require pharmaceutical manufacturers to provide a discount equal to no less than 30 percent of the negotiated price for brand drugs, biologics, biosimilars, and high-cost generic drugs.**

RATIONALE 5 - 1

At the start of the Part D program, plan sponsors had strong incentives to manage their enrollees' drug spending because most of their revenues took the form of fixed-dollar premiums and capitated payments from Medicare. Over time, changes in law and in spending patterns have significantly reduced plans' financial liability for benefits and eroded their incentives to manage spending. Plans' small liability in the coverage gap and catastrophic phases of the benefit have led to incentives for Part D sponsors to place certain high-price, high-rebate products on their formularies. Some manufacturers find that increasing their prices allows them to offer larger rebates than their competitors and gain favorable formulary placement while paying comparatively small coverage-gap discounts. In other words, manufacturers do not bear much of the effects of their price increases as directly as they would if the discount applied in the catastrophic phase of the benefit. Meanwhile, beneficiaries pay coinsurance based on high list prices for some of those drugs, potentially reaching Part D's OOP threshold more quickly than if the

plan sponsor had instead selected lower priced therapies for their formulary. The coverage-gap discount also distorts beneficiary and plan incentives because it makes the brand-name drugs cheaper relative to generic drugs. Beneficiaries who reach the OOP threshold pay 5 percent coinsurance with no upper limit. Because Medicare subsidizes nearly 75 percent of basic benefits, the financial burden on taxpayers is likely higher than it would be if policymakers restored Part D to its original approach of using more risk-based payments with stronger incentives for plans to manage benefit spending.

The discount in the catastrophic phase could be set at a higher rate to offset other costs of the restructured benefit. Alternatively, policymakers could choose to pay for the restructured benefit through higher enrollee premiums, higher Medicare program spending, or both. The Commission chose a manufacturer discount rate of at least 30 percent to include manufacturers among the stakeholders that would bear strong direct effects of drug price increases. A 30 percent discount would also help offset what would otherwise be increases in enrollee premiums and Medicare program spending resulting from Part D's new benefit structure.

As part of our recommendation, the reduction in reinsurance payments and increase in plan liability for catastrophic spending would be phased in during a transition period. (The other elements of the new benefit structure—eliminating the coverage gap, replacing the coverage-gap discount program with a new discount program in the catastrophic phase, and adding an annual cap on beneficiary OOP costs—could be implemented without a transition.) We have suggested a transition period of four years, but policymakers could consider a shorter or longer period. A longer transition would give plans more time to adjust to the new benefit structure and allow policymakers to respond to any unexpected outcomes before the new structure is fully phased in. However, a longer transition would also leave some of the current system's misaligned incentives in place longer and potentially inhibit the entrance into the market of new Part D sponsors.

RECOMMENDATION 5-2

Concurrent with our recommended changes to the benefit design, the Congress should:

- **Establish a higher copayment amount under the low-income subsidy for nonpreferred and nonformulary drugs.**

- **Give plan sponsors greater flexibility to manage the use of drugs in the protected classes.**
- **Modify the program's risk corridors to reduce plans' aggregate risk during the transition to the new benefit structure.**

RATIONALE 5-2

The second recommendation would provide plan sponsors with stronger formulary tools with which to manage enrollees' drug spending and negotiate lower prices. It would complement the first recommendation in that the combination of greater incentives (more of Medicare's subsidy through capitated payments) and stronger tools (more formulary flexibility) could lead plan sponsors to manage overall drug spending more effectively.

Plan sponsors routinely use differential cost sharing to make lower cost drugs and biologics more attractive to enrollees. However, since maximum cost sharing for LIS enrollees is set by law and plans cannot modify those amounts, sponsors have limited ability to manage drug spending for this population. Current LIS copayments provide much weaker financial incentives to choose lower cost medications than those faced by other enrollees. In particular, LIS enrollees have no financial incentive to choose brand-name drugs on a preferred tier over an alternative on a nonpreferred tier or a nonformulary drug. Under this recommendation, plans would make LIS enrollees and their prescribers aware of preferred therapeutic options as well as the relevant LIS copayment amounts.

Under the existing protected-class policy, plan sponsors must include all drugs in six therapeutic classes on their formulary. Even though plan sponsors may place utilization management requirements on protected-class drugs, their inability to exclude products from a plan's formulary prevents sponsors from using competitive pressure among alternative drug therapies to negotiate for manufacturer rebates. In turn, plan sponsors report that manufacturers offer fewer rebates on brand-name drugs in protected classes, and when they are available, the rebates are lower, on average (Johnson et al. 2018). The Commission has also noted higher than average increases in list prices of single-source drugs within some of the protected classes (Medicare Payment Advisory Commission 2020b).

By modifying Part D's current risk corridors, Medicare could place temporary aggregate limits on the amount of risk plans bear as they transition to the restructured benefit.

RECOMMENDATION 5-3

Concurrent with our recommended changes to the benefit design, the Secretary should:

- **Allow plans to establish preferred and nonpreferred tiers for specialty-tier drugs.**
- **Recalibrate Part D's risk adjusters to reflect the higher benefit liability that plans bear under the new benefit structure.**

RATIONALE 5-3

The third recommendation consists of complementary actions that the Commission believes the Secretary should take in coordination with the changes in law described in the first two recommendations. Given the rapid growth in the introduction of and Part D spending for specialty-tier drugs, plan sponsors need new tools with which to manage those therapies. By allowing plans to set differential cost-sharing requirements between competing specialty products, plan sponsors may be able to encourage their enrollees to use lower priced therapies. Plan sponsors may also gain more leverage in negotiating rebates with manufacturers.

Under a restructured benefit, Part D plans would receive less reinsurance from Medicare and higher capitated payments. CMS would recalibrate its RxHCC risk adjustment model to reflect the new higher average plan liability.

IMPLICATIONS 5-1, 5-2, AND 5-3

Spending

- The Congressional Budget Office estimates that the combination of the Commission's three recommendations would lead to one-year program savings of greater than \$2 billion relative to baseline spending and savings of greater than \$10 billion over five years. Separate estimates for each recommendation are not available.

Beneficiaries

- The restructured benefit would be a simpler design than Part D's current benefit in that cost sharing would be more predictable for beneficiaries, who would no longer experience three different structures

of cost sharing: one before they reach the initial coverage limit, one in the coverage gap, and one in the catastrophic phase.

- A new annual cap on OOP costs would lower cost sharing for enrollees who have high drug spending and would provide more complete financial protection for all enrollees. For beneficiaries who do not receive the LIS, the annual cap on OOP would eliminate cost barriers and improve access to medications, which in turn could increase the use of medications. The increase may enhance the health benefit of pharmaceutical care for some beneficiaries, while increasing polypharmacy could result in adverse health effects for others.
- Introducing differential cost sharing between plans' preferred and nonpreferred drugs would give LIS beneficiaries stronger financial incentives to use lower cost drugs. If beneficiaries switched to preferred therapies, those individuals would see no change in OOP spending. However, if a nonpreferred therapy was medically necessary, the beneficiary would have to pay the modestly higher copayment or pursue a tiering exception to obtain the nonpreferred therapy at a preferred (lower) copayment. Because the higher nonpreferred copayment would also apply to drugs not on a plan's formulary (nonformulary drugs), a beneficiary who obtained a nonformulary drug through the plan's exceptions process would also pay somewhat higher cost sharing than under current law. In those situations, we expect that plan sponsors would make LIS enrollees and their prescribers aware of the tier placement of the prescribed drug, preferred alternatives, and relevant LIS copay amounts.
- If plan sponsors offered a benefit with two specialty tiers (preferred and nonpreferred), beneficiaries who chose medications on the preferred specialty tier would benefit from lower cost sharing. If a nonpreferred specialty-tier product was medically necessary, the beneficiary would have to pay the higher cost sharing or pursue a tiering exception to obtain the nonpreferred product at the lower cost sharing that applied to the preferred specialty tier (or, in the case of an LIS beneficiary, the lower copayment set in law for preferred drugs).
- Part D has multiple beneficiary protections that would help ensure that all enrollees had continued access to clinically appropriate medications. One

such protection relates to CMS’s formulary review that ensures broad coverage of medications. Plans must include at least two distinct drugs per class on their formularies. Beneficiaries would face somewhat higher cost sharing only if they and their prescriber selected a nonpreferred product over the preferred therapy. Under this policy change, beneficiaries would have access to a tiering exceptions process that would allow them to obtain the nonpreferred-tier drug at the lower, preferred cost sharing when the use of a nonpreferred-tier drug is medically necessary.

- The effects of our recommendations on enrollee premiums would depend on multiple factors and would vary by plan. On the one hand, plan sponsors would have more formulary tools and stronger incentives to manage their enrollees’ spending. That, in turn, would tend to lower benefit costs and enrollee premiums. However, the increased generosity of the Part D benefit would tend to put upward pressure on costs and premiums. If the change in plan formularies or benefit structure resulted in more requests for exceptions and appeals cases, that could result in higher administrative costs, a portion of which would be reflected in enrollee premiums. Eliminating the coverage gap and beneficiary cost sharing in the catastrophic phase would increase the costs of Part D’s basic benefit, which in turn could lead to higher enrollee premiums. However, a new manufacturer discount of 30 percent or more of catastrophic spending could offset most if not all of those higher benefit costs. If, under this policy change, enrollee premiums for basic benefits increased, a small share of beneficiaries could choose not to enroll in Part D. However, given that Medicare would continue to subsidize about 75 percent of the costs of the basic Part D benefit, we expect that most enrollees would remain in the program.

Plans

- Plan sponsors would be responsible for a larger share of catastrophic benefits than they are today, and Medicare’s reinsurance payments would be smaller. Because this recommendation would reduce Medicare’s reinsurance and increase plans’ capitated payments, plan sponsors would bear more insurance risk for their enrollees’ benefit spending. In general, we expect this approach would give plan sponsors stronger incentives to manage enrollees’ spending and reduce incentives for sponsors to put

high-price, high-rebate drugs on their formularies. If the recommendations are implemented, the Commission intends to monitor the aggregate amount of manufacturer rebates to observe whether the policy changes achieve their intended effect of reducing the misaligned incentives with respect to postsale rebates.

- Plan bids would be higher under the restructured benefit, and plan sponsors would receive higher capitated direct subsidy payments from Medicare. CMS would recalibrate Part D’s risk adjustment system to reflect the predictably higher benefit spending in Medicare’s capitated payments. Because of changes in law to close the coverage gap, CMS has experience updating its risk adjustment model on a regular basis. Under Part D’s risk adjustment model, with separate risk adjusters for LIS beneficiaries, CMS would be able to recalibrate the model to account for the disproportionate impact that the reform package would have on the average capitated payments for LIS beneficiaries. In addition, a transition period would allow CMS to monitor the adequacy of risk-adjusted payments and any impact on plan sponsors’ incentives for risk selection.
- Under the restructured benefit, plan sponsors would have more formulary tools to manage benefit spending, which in turn could lower basic benefit costs and enrollee premiums. By changing the LIS copay structure to add a new higher copayment for medications placed on a nonpreferred tier or for nonformulary drugs, plan sponsors would have an important new tool for managing spending for LIS enrollees. A new higher LIS copayment amount for nonpreferred or nonformulary drugs would also give plan sponsors greater leverage with manufacturers.
- With greater flexibility to manage drugs in the protected classes, plan sponsors would have more leverage to negotiate price concessions for protected-class drugs for which competition exists among drug manufacturers. Allowing plan sponsors to use two specialty tiers (preferred and nonpreferred) would provide a new tool to encourage the use of preferred therapies on a specialty tier, while at the same time giving sponsors leverage in their negotiations for rebates among manufacturers of drugs and biologics with high prices. This ability to structure competition among specialty products would allow plan sponsors to encourage the use of biosimilars (when they become available) and could facilitate

further development of biosimilar products. At the same time, if more beneficiaries sought exceptions for nonpreferred or nonformulary drugs, plans could have higher administrative costs associated with their exceptions and appeals process. That, in turn, could put upward pressure on plan bids and premiums.

- The new 30 percent manufacturer discount in the catastrophic phase could help limit growth in drug prices and offset Part D's basic benefit costs. If policymakers structured the discount rate so that it was indexed to growth in some benchmark measure of price inflation (such as in average Part D spending) and could potentially increase in later years, policymakers could consider lowering Medicare's reinsurance by the same amount as each incremental increase in the discount rate. If the discount rate increases led instead to a reduction in plan liability, that reduction could weaken plan incentives to manage spending.
- Replacing the coverage-gap discount program with a new manufacturer discount in the catastrophic phase would have a disproportionate impact on EGWPs. If EGWP sponsors continued to provide supplemental benefits that prevented or delayed enrollees from reaching the catastrophic phase of the benefit, they would receive fewer manufacturer discounts than they do now. At the same time, because CMS would need to go through the rule-making process to implement the restructured benefit, we expect employers would have time to adjust their benefit offerings or switch to providing the prescription drug benefit through a plan that is eligible for the retiree drug subsidy before facing the full financial impact of the reforms.
- The Commission believes it is important to transition to the new benefit structure over a period of several years partly out of concern for the stability of smaller MA-PDs that serve larger numbers of LIS enrollees. The reduction in reinsurance payments and increase in plan liability for catastrophic spending would be phased in so that plan sponsors could adjust to the new distribution of risk. (The other elements of the new benefit structure—eliminating the coverage gap, replacing the coverage-gap discount program with a new discount program in the catastrophic phase, and adding an annual cap on beneficiary OOP costs—would be implemented without a transition.) During the transition period, CMS would be able to monitor and evaluate plan sponsors' progress at

using new flexibilities for managing benefit spending while still providing beneficiaries with appropriate access to medicines. A transition period would give policymakers time to identify and address any unexpected outcomes with the implementation of the new benefit.

- We have suggested a transition period of four years, but policymakers could consider a shorter or longer period. A longer transition would give plans more time to adjust to the new benefit structure and would allow policymakers to respond to any unexpected outcomes before the new structure was fully phased in. However, it would also leave some of the current system's misaligned incentives in place longer and potentially inhibit the entrance into the market of new Part D sponsors. Modifying Part D's risk corridors would provide greater financial protection during the transition to a new benefit structure. The enhanced protection could take the form of a tighter range around plan bids in which plans would be at full risk for their benefit spending, changes to the shares of gains or losses borne by Medicare and plans, or both. The modifications would be available to all plan sponsors. However, such measures would be especially important to smaller sponsors of regional MA-PDs that have larger proportions of LIS enrollees.

Pharmaceutical manufacturers

- Restructuring Part D's benefit to remove the brand manufacturer discount in the coverage gap and establishing a new manufacturer discount in the catastrophic phase would affect individual pharmaceutical manufacturers differently, depending on the products they make. Manufacturers of relatively lower priced products that now pay a sizable share of the coverage-gap discounts might see higher revenues because they would no longer need to discount their products in the coverage gap. Producers of higher priced products would pay proportionately more of the new discount.
- The new manufacturer discount in the catastrophic phase could potentially restrain manufacturers' incentives to increase drug prices. The discount could be more effective at restraining price increases if it were structured so that the discount rate increased if the average price of the drugs subject to the discount increased faster than a benchmark (such as

average Part D spending). However, the effects on manufacturers' pricing decisions would likely vary, depending on the manufacturer's Medicare market share and the degree of competition among therapeutic alternatives. There is also uncertainty as to whether the policy change would restrain or worsen the growth in launch prices of new therapies.

- New formulary tools would allow plan sponsors to bargain harder for higher rebates or reduce enrollees' use of products that offered low or no rebates through the use of nonpreferred tiers. For certain protected-class drugs, there could be products that would no longer be included on plans' formularies. As a result, some manufacturers could experience lower Part D revenues or diminished ability to raise prices of their products.
- A 30 percent manufacturer discount on catastrophic spending would likely constrain the profitability of

new specialty drugs and potentially reduce incentives to invest in the research and development (R&D) of such products. Two key issues to consider are the magnitude of potential investment reductions in pharmaceutical R&D that may result from the policy change and the value of drugs that subsequently would not be developed (Ginsburg and Leiberman 2020). Some stakeholders contend that more investment resources are needed to pursue breakthrough drugs. Others believe that the current pool of resources already permits some projects to be funded that are of limited value. Because the new discount is more likely to apply to high-priced drugs and biologics, the policy change could steer investments in pharmaceutical R&D away from such products and toward drugs to address complicated aspects of more prevalent conditions (Gottlieb and Ippolito 2019). ■

Endnotes

- 1 The amount of gross prescription drug spending needed to reach Part D's OOP threshold varies by individual, depending on LIS status and the mix of brand and generic prescriptions an enrollee fills.
- 2 In 2020, 150 percent of the federal poverty guideline was \$19,140 for an individual or \$25,860 for a couple.
- 3 This figure is based on a volume-weighted Part D price index constructed by Acumen LLC, using prices paid at the point of sale (POS). The indexes do not reflect postsale rebates or discounts from manufacturers and pharmacies. POS prices are the relevant metric for determining when a beneficiary has reached the OOP threshold.
- 4 The figure (\$13 billion) for low-income cost-sharing subsidies for prescriptions filled during the coverage gap is an estimate that reflects our internal algorithm to apportion claims that straddle multiple phases of the benefit.
- 5 Under law, Medigap policies may not cover Part D cost sharing, but they do cover cost sharing for Part B drugs.
- 6 Like PDPs, MA-PDs can offer either basic coverage or enhanced coverage. Almost all beneficiaries in traditional MA-PDs (about 95 percent) are in plans that offer enhanced coverage, while most beneficiaries in D-SNPs (about 80 percent) are in plans that offer basic coverage.
- 7 Medicare also has other types of health plans that include Part D coverage but are not classified as MA-PDs because they operate outside of the MA program. Two types of plans—Medicare-Medicaid Plans and the Program of All-Inclusive Care for the Elderly—are made up almost entirely of LIS beneficiaries, but in 2019 their share of the overall LIS population was only 3 percent.
- 8 The PBM market is highly concentrated, and the three largest PBMs are owned by major insurers that also compete with smaller plans in some geographic markets: CVS Caremark (owned by CVS Health, which owns Aetna), Express Scripts (owned by Cigna), and OptumRx (owned by UnitedHealth Group). Given the dominant position of the large PBMs and the importance of obtaining postsale rebates under Part D's current structure, new plan sponsors could have difficulty entering the Part D market because they face greater uncertainty about their plans' enrollment and manufacturers would be less likely to negotiate larger rebates with them. Going forward, policymakers could consider other approaches to ensure that new plan sponsors with innovative approaches to service delivery can enter the Part D market.
- 9 Under the RDS, Medicare provides a tax-free subsidy to an employer for 28 percent of each eligible retiree's drug costs that fall within a specified range of spending.
- 10 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 benefits in commercial populations. Some of those policies are consistent with the Commission's 2016 recommendations.
- 11 A few drug categories are excluded by statute, such as agents used for weight loss or gain, to promote fertility, for cosmetic purposes or hair growth, or for symptomatic relief of cough and colds.
- 12 Although plan sponsors tend to use coinsurance for nonpreferred and specialty tiers, one can get a sense of their magnitude in dollar terms because CMS prohibits plans from charging more than \$100 for nonpreferred drugs and limits specialty tiers to drugs that cost more than \$670, which means that the median coinsurance of 25 percent on a specialty tier drug is at least \$167.50 (Centers for Medicare & Medicaid Services 2019a).
- 13 For example, CMS could consider granting exceptions from the requirement for plans to put two drugs per class (or type) on their formulary if over-the-counter alternatives were available or if one of the drugs that plans would normally have to cover was an extended-release version of an existing product. In 2018, a CMS proposed rule would have permitted plans to exclude extended-release versions of protected-class drugs from their formularies, but the policy changes were not finalized.
- 14 Most Part D plans have a specialty tier, but not all plans place every high-cost specialty drug on a specialty tier. Cost-sharing amounts on specialty tiers range from 25 percent to 33 percent of pharmacy (point-of-sale) prices. The industry does not have one consistent definition of specialty drugs, but these drugs tend to be characterized as high cost and are used to treat rare conditions, require special handling, use a limited distribution network, or require ongoing clinical assessment (Doshi et al. 2016).
- 15 The Congressional Budget Office found that, in 2015, manufacturer rebates averaged 10.5 percent for specialty drugs compared with 28.4 percent for nonspecialty brand-name drugs (Congressional Budget Office 2019).
- 16 For example, differential cost sharing would not apply to beneficiaries who receive Medicaid nursing home care. These beneficiaries are typically required to use all their income—

except for a very modest personal need allowance (often \$30 per month) and a spousal allowance, if applicable—to help pay for their care, which is why the LIS fully covers their cost sharing.

- 17 CMS’s proposal would have established additional exceptions to allow Part D sponsors to (1) implement broader use of prior authorization and step therapy requirements for protected-class drugs, including to determine use for protected-class indications; (2) exclude a protected-class drug from a formulary if the drug was a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remained on the market; and (3) exclude a protected-class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified period. (These exceptions from the protected-class policy would not have superseded other Part D formulary requirements, such as plan sponsors’ obligation to cover two distinct drugs in each drug class.)
- 18 For example, the base payment rate in 2020 for a 73-year-old female who lives in the community is \$383 for an LIS beneficiary and \$247 for a beneficiary without the LIS. In addition, the added payments based on diagnosis codes are often higher for LIS beneficiaries: If the same 73-year-old also has diabetes without complications, Medicare will pay an additional \$332 for an LIS beneficiary and \$280 for a beneficiary without the LIS.
- 19 However, the Commission has consistently found that, under the MA program’s similar model for risk-adjusting payments (the CMS–hierarchical condition category, or CMS–HCC, model), special needs plans, which serve certain types of high-cost beneficiaries, have higher profits than MA plans that serve a broad range of beneficiaries (Government Accountability Office 2013, Medicare Payment Advisory Commission 2020b).

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