

CHAPTER

6

Improving Medicare Part D

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

- 6-1** The Congress should change Part D to:
- transition Medicare’s individual reinsurance subsidy from 80 percent to 20 percent while maintaining Medicare’s overall 74.5 percent subsidy of basic benefits,
 - exclude manufacturers’ discounts in the coverage gap from enrollees’ true out-of-pocket spending, and
 - eliminate enrollee cost sharing above the out-of-pocket threshold.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

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- 6-2** The Congress should change Part D’s low-income subsidy to:
- modify copayments for Medicare beneficiaries with incomes at or below 135 percent of poverty to encourage the use of generic drugs, preferred multisource drugs, or biosimilars when available in selected therapeutic classes;
 - direct the Secretary to reduce or eliminate cost sharing for generic drugs, preferred multisource drugs, and biosimilars; and
 - direct the Secretary to determine appropriate therapeutic classifications for the purposes of implementing this policy and review the therapeutic classes at least every three years.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

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- 6-3** The Secretary should change Part D to:
- remove antidepressants and immunosuppressants for transplant rejection from the classes of clinical concern,
 - streamline the process for formulary changes,
 - require prescribers to provide standardized supporting justifications with more clinical rigor when applying for exceptions, and
 - permit plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

Improving Medicare Part D

Chapter summary

In 2015, more than 39 million Medicare beneficiaries received outpatient prescription drug coverage through Part D. A key goal for the Part D program is to ensure that beneficiaries have access to appropriate medications, while keeping the program financially sustainable to taxpayers. Under Part D, Medicare subsidizes 74.5 percent of the cost of basic drug benefits, and enrollees pay the remaining 25.5 percent through premiums. Medicare pays plan sponsors the 74.5 percent subsidy in two forms: (1) capitated direct-subsidy payments that are based on plan bids and (2) open-ended reinsurance on individual enrollees that covers 80 percent of drug spending above Part D's out-of-pocket (OOP) threshold (which occurs at an estimated average of \$7,515 in total drug spending for 2016). Medicare also pays plans for some or all premiums and cost sharing on behalf of about 12 million beneficiaries who qualify for and enroll in the program's low-income subsidy (LIS).

The current structure of Part D reflects a system of federal subsidies and regulations that was designed to encourage broad participation of Medicare beneficiaries and private plan sponsors in a new program. However, since the launch of the program in 2006, the market for Medicare Advantage–Prescription Drug plans has grown substantially, and the market for stand-alone prescription drug plans is firmly established, so it is appropriate to consider whether the program's incentives need to be restructured to better ensure financial sustainability.

In this chapter

- Introduction
- Goals for Part D and the case for change
- Potential improvements to Part D

Financial sustainability is a growing concern because of sizable increases in program expenditures for high-cost enrollees (those who reach Part D's OOP threshold), which have been driven by increases in the numbers of non-LIS enrollees reaching the OOP threshold and increases in the average price of prescriptions they fill (which reflect both growth in drug prices and changes in the mix of drugs used). Going forward, many new biopharmaceutical products in the development pipeline will have substantially higher prices than previous treatments, even when the drugs have therapeutic competitors. This trend will exert strong upward pressure on premiums, beneficiary cost sharing, and program costs.

In keeping with the program's market-based approach, the Commission recommends improvements intended to prepare Medicare's prescription drug program for the future. Collectively, the recommendations make up a package of interrelated steps. One set of changes would give plan sponsors greater financial incentives and stronger tools to manage the benefits of high-cost enrollees. Medicare's overall subsidy of basic Part D benefits would remain unchanged at 74.5 percent, but plan sponsors would receive more of that subsidy through capitated payments rather than open-ended reinsurance. Over a transition period, Medicare would significantly lower the amount of reinsurance it pays plans from 80 percent of spending above Part D's OOP threshold to 20 percent. When combined with the Commission's recommendation to provide greater OOP protection, the insurance risk that plan sponsors shoulder for catastrophic spending would rise commensurately from 15 percent to 80 percent. At the same time, plan sponsors would be given greater flexibility to use formulary tools to manage benefits. Other parts of the Commission's recommendations would exclude manufacturer discounts on brand-name drugs from counting as enrollees' true OOP spending, but would also provide greater insurance protection to all non-LIS enrollees through a real OOP cap (although some enrollees would incur higher OOP costs than they do today). The recommended improvements would also moderately increase financial incentives for LIS enrollees to use lower cost drugs and biologics.

Under the combined recommendations, Part D's set of risk adjusters would become more important as a tool for counterbalancing plan incentives for selection, and CMS would need to take steps to recalibrate the risk adjustment system. Similarly, because plans would have greater flexibility to use management tools, CMS would need to continue monitoring plan operations, such as reviewing formularies and pharmacy networks, to ensure beneficiary access. The agency would also need to ensure that the appeals and grievance procedures under Part D function effectively.

The net impact of the Commission's recommendations restrains overall drug costs and makes the benefit more affordable for beneficiaries and taxpayers in the long

run. The recommendations enhance the Part D benefit so that the program would provide real insurance protection against catastrophic OOP spending. However, the recommendations would also expose some beneficiaries to higher cost sharing in the coverage gap. To the extent that the adoption of this combined set of recommendations results in net program savings, the Congress could consider enhancing protections for non-LIS beneficiaries facing high cost-sharing burdens. ■

Introduction

Part D began in 2006, and by many measures, this program for providing Medicare beneficiaries with access to outpatient prescription drugs has been a success. Using a market-based approach, Part D expanded access to medicines for the Medicare population. Part D uses competing private plans to deliver benefits. That competition has given beneficiaries a broad choice of plans while generally keeping down growth in enrollee premiums. Repeated surveys indicate that 85 percent or more of enrollees are satisfied with their coverage.

However, the environment in which Part D operates has changed. Part D was launched when patents on many widely used brand-name drugs were expiring. Plan sponsors have used formularies, pharmacy networks, and differential cost sharing to encourage enrollees to use lower cost drugs. These practices, combined with the fortuitous timing of patent expirations, have led to a dramatic shift toward the use of generics. At the same time, increases in program expenditures have been driven by spending for high-cost enrollees (those who reach Part D's out-of-pocket (OOP) threshold). Since the enactment of the Patient Protection and Affordable Care Act of 2010 (PPACA), changes in what counts as the enrollee's own OOP spending have led to more enrollees reaching the OOP threshold. Concurrently, the average price of prescriptions filled by high-cost enrollees has increased sharply (affected by changes in both the price and mix of drugs). For the future, many biopharmaceutical products in the development pipeline will have substantially higher prices than previous treatments, which will exert upward pressure on premiums and program costs.

In 2014, Medicare spent almost \$78 billion on its Part D benefit covering outpatient prescription drugs.¹ The program finances drug benefits for individuals enrolled in private stand-alone prescription drug plans (PDPs), in Medicare Advantage–Prescription Drug plans (MA–PDs), and in employer plans that receive Part D's retiree drug subsidy (RDS). In 2015, 39 million Medicare beneficiaries (70 percent) were enrolled in Part D plans; over three-fifths were in PDPs, with the remainder in MA–PDs (Medicare Payment Advisory Commission 2016). Medicare also pays Part D plans for some or all premiums and cost sharing on behalf of about 12 million beneficiaries who qualify for and enroll in the program's low-income subsidy (LIS), including those dually eligible for Medicare and Medicaid. In 2015, 30 percent of Part D enrollees received the LIS,

and 70 percent of LIS enrollees were in PDPs (Medicare Payment Advisory Commission 2016).

A defined standard benefit

Part D's defined standard basic benefit has a structure that, for 2016, includes a \$360 deductible and 25 percent coinsurance until the enrollee reaches \$3,310 in total covered drug spending, called the initial coverage limit (Figure 6-1, p. 162). Enrollees with spending higher than the initial coverage limit face higher cost sharing (45 percent for brand-name drugs and 58 percent for generic drugs)—commonly called the coverage gap—up to a threshold of \$4,850 in OOP spending (at an estimated average of \$7,515 in total drug spending). That threshold is also known as a “true OOP” cap because it excludes cost sharing paid on behalf of a beneficiary by most sources of supplemental coverage such as employer-sponsored policies and enhanced benefits provided by Part D plans. An exception to the true OOP approach relates to a 50 percent manufacturer discount on brand-name drugs purchased in the coverage gap. Under PPACA, manufacturers must provide that discount as a condition for Part D to cover their drugs, and the 50 percent discount is added to the enrollee's own spending for purposes of determining whether the enrollee has reached the OOP threshold. Part D's basic benefit is scheduled to become more generous in 2020, when enrollees will pay 25 percent cost sharing until they reach the OOP threshold. Above that threshold, enrollees will pay the greater of 5 percent coinsurance or \$2.95 to \$7.40 per prescription.

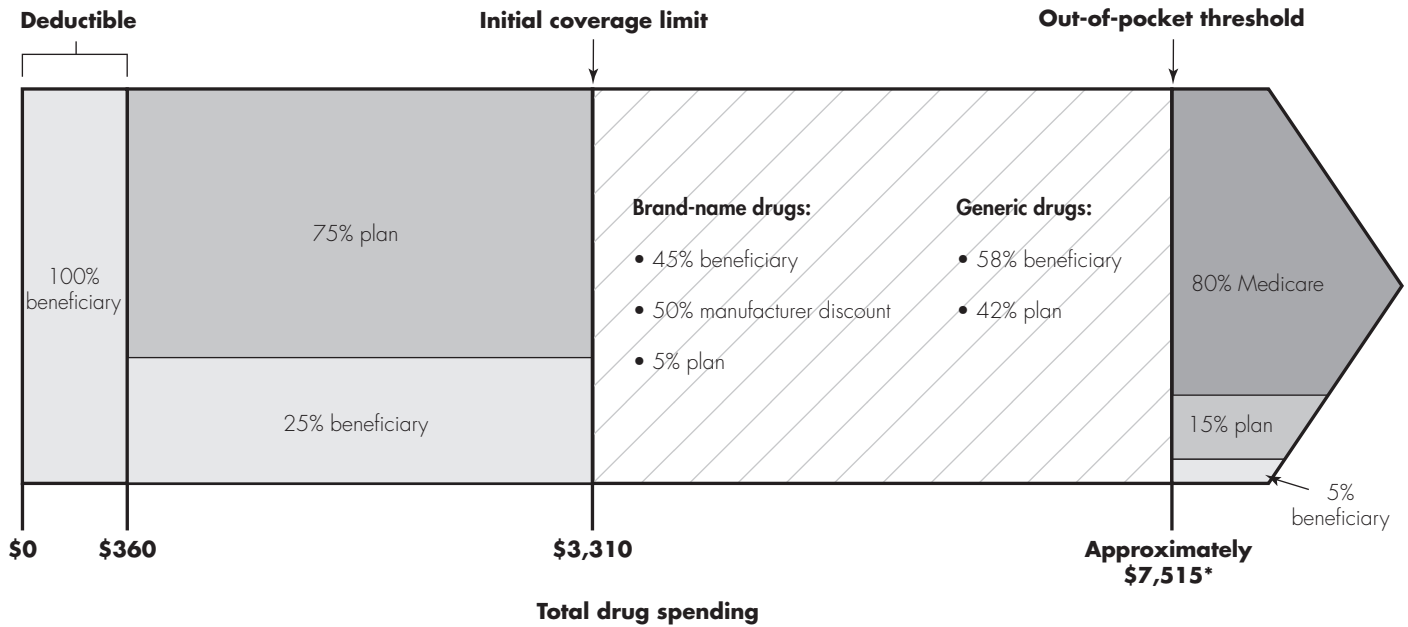
Less than 1 percent of Part D enrollees are in plans that use this defined standard benefit; the rest are in plans that are actuarially equivalent to the standard benefit or are enhanced in some way (Medicare Payment Advisory Commission 2016). Actuarially equivalent plans have the same average benefit value as defined standard plans but a different benefit structure; for example, they may use tiered copayments that can be higher or lower for a given drug compared with the 25 percent coinsurance. Enhanced plans have a higher average benefit value, but Medicare does not subsidize the value of benefits above the average of the defined standard benefit; enrollees pay the full premium for additional benefits.

Medicare's payments to plans and mechanisms for sharing risk

Medicare pays Part D plans capitated amounts based on competitive bids, and the program pays more open-ended subsidies for enrollees with high drug spending.

FIGURE 6-1

Part D's defined standard benefit in 2016



Notes: Dollar amounts and benefits between the initial coverage limit and the out-of-pocket (OOP) threshold (also known as the coverage gap) reflect Part D's basic benefit structure in 2016.

*Total covered drug spending at the annual OOP threshold depends on each enrollee's mix of brand-name and generic drugs filled during the coverage gap. This amount is for an individual who does not receive Part D's low-income subsidy, has no other supplemental coverage, and has the average mix of generic and brand-name drug spending.

Source: MedPAC based on information from CMS, Office of the Actuary.

Combined, these payments subsidize premiums by about 74.5 percent; enrollees pay the remaining 25.5 percent in monthly premiums. To arrive at the amount of capitated payments, sponsors submit bids to CMS that represent their revenue requirements (including administrative costs and profit) for delivering basic drug benefits to an enrollee of average health. After reviewing bids, CMS applies a statutory formula to determine Medicare's per member per month prospective payment to plans (called the *direct subsidy*), which reduces premiums for all Part D enrollees. Because Medicare pays a fixed dollar amount, plan sponsors risk losing money if their enrollees' drug spending is higher than the combination of direct-subsidy payments and enrollee premiums.

However, plan sponsors do not bear all the risk; Medicare shares risk with sponsors through three mechanisms (Medicare Payment Advisory Commission 2015a). CMS risk adjusts direct-subsidy payments to keep sponsors from avoiding enrollees who use more drugs. Medicare pays plans individual reinsurance equal to 80 percent of covered

spending above Part D's OOP threshold. Part D uses risk corridors that limit each plan's overall losses or profits if actual benefit spending is much higher or lower than the plan sponsor anticipated.

A plan's share of LIS enrollees is important because LIS enrollees tend to have higher than average drug spending, and plan sponsors have fewer tools to manage that spending. Unlike other enrollees whose cost-sharing amounts are set by sponsors as a part of plans' benefit design, maximum cost-sharing amounts for LIS enrollees are set by law at nominal amounts. Similarly, under law, LIS enrollees face no coverage gap and no cost sharing above Part D's OOP threshold. Part D's risk adjustment system helps to mitigate the incentive to avoid LIS enrollees, who tend to have higher benefit spending. Plan sponsors also receive monthly prospective payments from Medicare for the plan's expected amount of cost-sharing liability for LIS enrollees based on estimates that sponsors submit with their bids and that CMS later reconciles with plans based on actual prescriptions filled.

Risk adjustment

CMS risk adjusts Medicare's direct-subsidy payments to plans to reflect the expected costliness of each enrollee. Risk adjustment is prospective in that each enrollee's diagnoses from a base year are used to predict Part D benefit spending for the subsequent payment year. Diagnosis codes are taken from medical visits (i.e., physician, hospital outpatient, and hospital inpatient) using information from both fee-for-service claims and Medicare Advantage (MA) data.

The prescription drug hierarchical condition category (RxHCC) model predicts only the Part D benefit spending that a plan sponsor would cover (called *plan liability*) rather than total drug spending. Specifically, the predicted spending excludes the value of Medicare's individual reinsurance subsidies for high-cost enrollees because that risk is borne by Medicare rather than by the plan.

In past years, the Commission raised questions about an earlier version of the RxHCC model—whether risk scores were effective at overcoming incentives to avoid LIS enrollees (Hsu et al. 2010, Hsu et al. 2009, Medicare Payment Advisory Commission 2009b). However, beginning in 2011, CMS refined its model to better capture differences in the mix of prescription drugs taken by categories of enrollees.² For example, among younger disabled enrollees who receive the LIS, there is generally a greater prevalence of conditions treated with multiple drugs, such as HIV/AIDS and mental illness compared with older nondisabled enrollees, and their drug spending may be costlier on average.

In 2014 and 2015, Commission staff interviewed plan and consulting actuaries about the performance of the current RxHCC model. All interviewees responded that the newer model is much improved for equalizing remuneration between LIS and non-LIS enrollees. However, several actuaries also said that the risk adjusters tend to undercompensate for enrollees who use high-cost specialty drugs.³ When a widely used, high-priced drug enters the market, CMS may need to modify certain RxHCCs to recognize lags that can occur between the entrance of new high-cost drugs and the point at which claims data become available to recalibrate risk adjustment models. 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.

In general, any changes to Part D's benefit structure that affect plan liability would be accompanied by a recalibration of the RxHCC model. Most recently, CMS recalibrated the RxHCC model in preparation for the 2017 benefit year. The agency re-estimated model coefficients to reflect a more recent year of Part D claims data (2014) and diagnosis information (2013). CMS also estimated how the gradual phaseout of Part D's coverage gap would affect plan liability. For example, in 2017, plan liability for non-LIS beneficiaries in the coverage gap is 49 percent for generic drugs and 10 percent for brand-name drugs (compared with 42 percent and 5 percent, respectively, in 2016). In some years, CMS also conducts a clinical review of condition categories, dropping some and adding others to use groupings that better reflect predictors of current costs. For example, for 2016, a new condition category was created for high-cost, secondary metastatic cancers and liver cancer. Another category was created for hepatitis C, separating it from other types of chronic viral hepatitis.

For 2016, CMS uses a risk adjustment model that was calibrated to prescription claims data from 2013—before the introduction of newer hepatitis C medications. To account for the higher cost of those treatments, CMS made a manual adjustment to reflect what the coefficient for chronic hepatitis C would have been if the newer drugs had existed in 2013. CMS noted that the hepatitis C situation is unusual, and the agency does not expect to make similar adjustments routinely (Centers for Medicare & Medicaid Services 2015a). For its 2017 payments, the agency will use a coefficient for hepatitis C drugs estimated from claims and diagnoses data that is lower than the factor used for 2016 payments (Centers for Medicare & Medicaid Services 2016b).

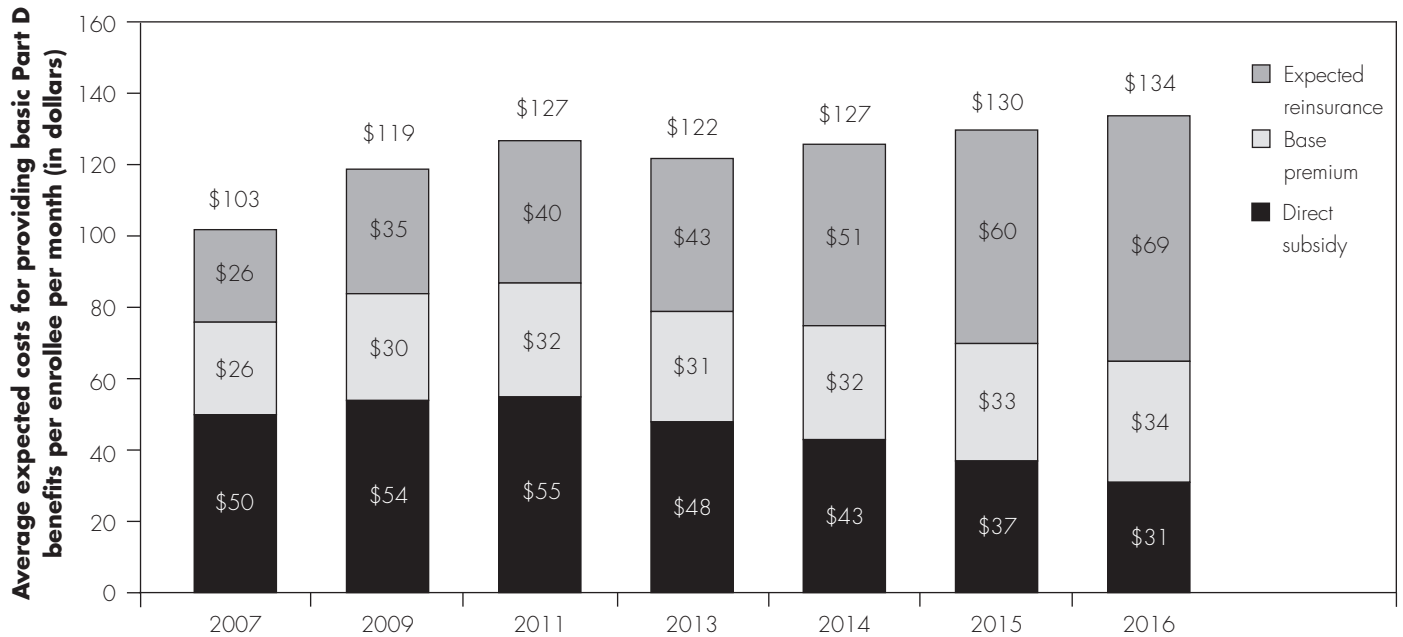
Individual reinsurance for high-cost enrollees

Medicare also subsidizes the Part D benefit and shares risk with plans through reinsurance. For individual enrollees with very high drug spending, Medicare pays plan sponsors 80 percent of covered benefits above Part D's OOP threshold (Figure 6-1). The remaining benefit spending is divided between the plan (15 percent) and the enrollee (5 percent). As with risk adjustment, individual reinsurance tempers the incentives for plans to avoid high-cost enrollees.

When plan sponsors submit their bids to CMS, they include an estimate of how much individual reinsurance the plan expects its enrollees will accrue. CMS uses this information to set prospective reinsurance payments to

FIGURE 6-2

Individual reinsurance has grown over time as a share of Part D's average expected monthly cost of providing basic benefits



Note: The averages shown are weighted by the previous year's plan enrollment. Amounts do not net out subsequent reconciliation amounts with CMS. Components may not sum to stated totals due to rounding.

Source: MedPAC based on data from CMS.

the plan, which the agency reconciles with the plan after the end of the benefit year. The proportion of the average basic benefit cost made up by individual reinsurance has grown each year since the start of Part D (Figure 6-2). In 2007, expected reinsurance made up about 26 percent of the average costs of providing basic benefits (\$26 of \$103). By 2016, this share grew to about 52 percent of the average benefit costs (\$69 out of \$134).

Risk corridors

A third mechanism by which Medicare shares risk with Part D plans is risk corridors, which limit 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. Administrative costs and supplemental benefits are not part of the Part D risk corridor calculation.

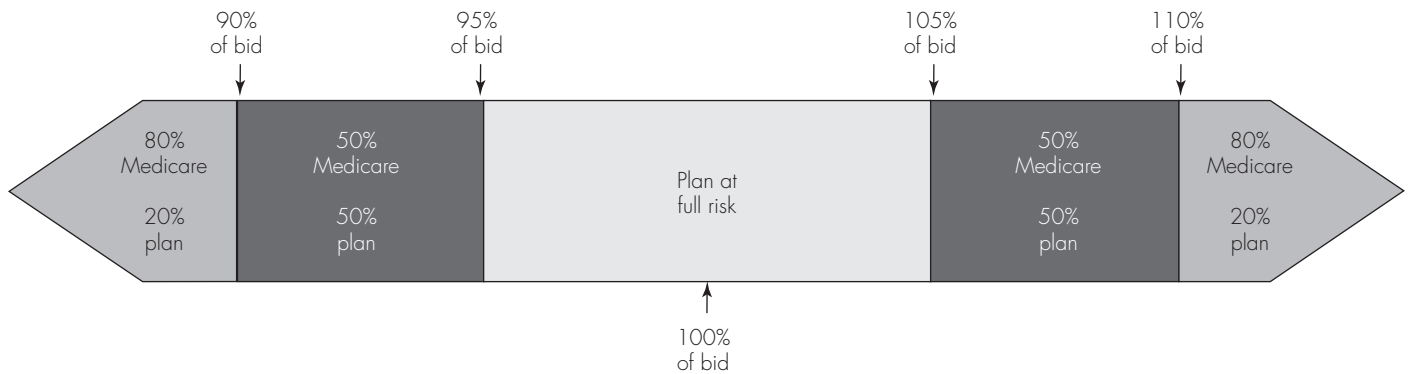
In contrast to Medicare's reinsurance that protects plans against unexpectedly high costs incurred by individual

enrollees, risk corridors provide a cushion at a plan level in the event of unforeseen high drug spending. For example, if use of an expensive new medication affected a plan more widely than the sponsor had anticipated, resulting in sizable losses, Medicare would share some of those losses. Plan sponsors submit their bids seven months before the start of a Part D benefit year. If circumstances change between when a sponsor submits its bid and when it delivers benefits, risk corridors provide a safety net.

Plan sponsors are at full risk for average monthly benefits within the range of 95 percent to 105 percent of the plan bid (Figure 6-3). 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, then Medicare splits the difference (between the bid and actual benefit spending) with the plan sponsor 50–50. Beyond 110 percent or below 90 percent, Medicare covers 80 percent of excess benefit costs (or recoups excess profits). Since 2012, the Secretary of Health and Human Services has had authority to change the structure of Part D's risk

**FIGURE
6-3**

Risk corridors are in place for each Part D plan



Source: MedPAC depiction of Part D risk corridors as set by law.

corridors as long as she keeps at least the same amount of plan risk as in 2011 (i.e., widen risk corridors by adjusting the threshold percentages). Medicare recoups any amounts owed by withholding them from future monthly payments.

In our 2015 report to the Congress, the Commission discussed whether Part D’s risk corridors were still necessary (Medicare Payment Advisory Commission 2015a). Initially, the corridors were put in place to encourage the creation of a market for stand-alone PDPs. The year 2016 marks Part D’s 11th year, and the market for PDPs is now firmly established. Arguably, risk corridors are no longer needed. At the same time, each year between 2006 and 2014, the majority of Part D plan sponsors have made risk-corridor payments to Medicare because they earned substantially higher profits than they had built into their plan bids. Keeping Part D’s risk corridors in place, at least temporarily, would limit excess plan profits.⁴ Given changes the Commission is recommending to increase the share of risk assumed by plan sponsors and the uncertainty sponsors face associated with prices and spending on new specialty and biologic products, the Commission does not contemplate changes to the risk corridors at this time.⁵

Goals for Part D and the case for change

A key goal for the Part D program is to ensure that Medicare beneficiaries have access to appropriate

medications while it remains financially sustainable to taxpayers. That goal involves managing medication therapies—that is, finding a balance between encouraging adherence to appropriate medicines while mitigating concerns that may arise with polypharmacy (see text box on adherence and polypharmacy, pp. 166–167). The current structure of Part D still reflects a system of federal subsidies and regulations that was designed to encourage broad participation of Medicare beneficiaries and private plan sponsors in a new program. Now that the market for MA–PDs has expanded and the market for stand-alone PDPs is in place, it is appropriate to consider whether the program’s incentives need to be restructured to better ensure financial sustainability.

Recent trends in program spending are unsustainable

Evidence on program spending gives a mixed picture about the success of Part D plans at containing costs. Spending for the competitively derived direct-subsidy payments on which sponsors bear the most insurance risk has grown slowly, while benefit spending on which sponsors bear no insurance risk (low-income cost sharing) or limited risk (the catastrophic portion of the benefit, for which Medicare provides 80 percent reinsurance) has grown much faster (Medicare Payment Advisory Commission 2016).

From 2007 through 2014, Part D spending increased from \$46 billion to \$73 billion, a nearly 60 percent increase and

Balancing concerns about adherence and polypharmacy

Access to medications is an important tool for treating disease. Because most Medicare beneficiaries have chronic conditions—often multiple ones—typically, they need to use medication over time to ensure its therapeutic value (Lorgunpai et al. 2014).

Medication adherence refers to the degree to which a patient follows a prescriber’s recommendations for a drug therapy. By some estimates, 20 percent to 30 percent of prescriptions are never filled, and in 50 percent of cases, patients do not take a medication as prescribed (Brown and Bussell 2011, Ho et al. 2009). Public health officials and health literature report that poor medication adherence is associated with avoidable hospitalizations, sizable nondrug medical costs, and mortality. Because of the therapeutic importance

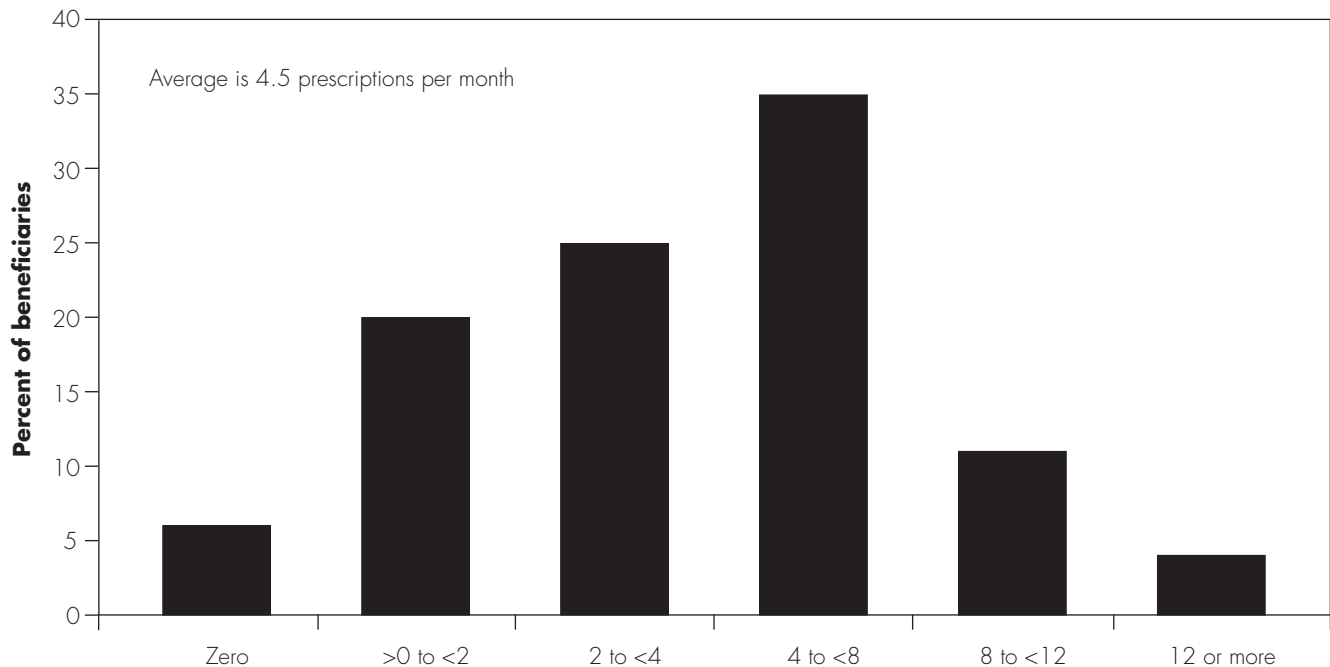
of certain classes of drugs (e.g., those used to treat cardiovascular diseases), measures of medication adherence are included among Part C (private plans that deliver medical benefits) and Part D quality measures and are a factor in the star ratings.

Within the Medicare population, the relative benefits and risks of drug therapies are less clear because of the risk of polypharmacy—the use of multiple medications (Lorincz et al. 2011).⁶ Clinical trials that evaluate the safety and effectiveness of new drugs rarely have patient populations that look like the Medicare population. For example, trials may use participant inclusion criteria such as having some minimum remaining life expectancy or exclusion criteria associated with history of other diseases. Medicare beneficiaries are elderly or disabled and typically receive treatment for multiple

(continued next page)

FIGURE 6-4

Number of prescriptions filled per month by Part D enrollees, 2013



Note: Number of prescriptions is standardized to a 30-day supply. Average number of prescriptions filled per month is estimated by taking the annual total prescriptions filled by Part D enrollees who were enrolled in the program for the full year in 2013. Percentages may not sum to 100 due to rounding.

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

Balancing concerns about adherence and polypharmacy (cont.)

chronic conditions—often through multiple prescribers. Our analysis of claims from 2013 shows that nearly three-quarters of Part D enrollees filled two or more prescriptions per month, and about half of enrollees filled four or more per month (Figure 6-4). A recent study found that in 2011, 15 percent of older adults were at potential risk of major interactions among their prescription drugs, over-the-counter medications, and dietary supplements compared with 8 percent in 2005 (Qato et al. 2016). Part D plans are required to have medication therapy management (MTM) programs to improve quality of pharmaceutical care for high-risk beneficiaries, but the Commission has been concerned about their effectiveness (Medicare Payment Advisory Commission 2016). Beginning in 2017, CMS will test whether prescription drug plan payment incentives and regulatory flexibility can lead to more effective MTM interventions.

Some Medicare beneficiaries have medical problems caused or exacerbated by polypharmacy. Adverse effects of polypharmacy can occur when a patient is prescribed more drugs than are clinically warranted or when all the prescribed medications are appropriate, but the total is too many for the patient to ingest or manage safely (Haque 2009). Individuals ages 65 and older are at high risk for adverse drug events associated with polypharmacy, yet there are few clinical guidelines pertinent to prescribing and managing multiple medications for this population (Lorgunpai et

al. 2014). A literature review of 16 studies (based on Medicare data) found polypharmacy to be a statistically significant predictor of hospitalization, nursing home placement, death, hypoglycemia, fractures, decreased mobility, pneumonia, and malnutrition (Frazier 2005). Polypharmacy among Medicare beneficiaries has also been associated with cognitive decline, falls, and urinary incontinence (Maher et al. 2014). One study of an elderly, community-dwelling population found no adverse events or deaths from systematically discontinuing many of their medications, and 88 percent of study subjects reported global improvements in their health (Garfinkel and Mangin 2010).

Because of the potential risks of polypharmacy, the relationship between medication adherence and health spending for individuals who are treated with multiple medications can differ from that for relatively healthier individuals. For example, adhering to multiple drug regimens could result in drug–drug interactions that affect a patient’s medical condition and lead to additional physician visits, emergency department visits, and hospitalizations. In its June 2014 report, the Commission examined the effects of medication adherence on health spending for the Medicare population (Medicare Payment Advisory Commission 2014b). We found that the effects of adherence vary by medical condition and range from modest savings to increased costs. We also found it difficult to control for all the factors that can influence this relationship. ■

an average annual growth rate of about 6.8 percent (Table 6-1, p. 168).⁷ Medicare’s direct-subsidy payments to plans grew slowly between 2007 and 2014, at an average annual rate of 1.5 percent. Over the same period, Medicare’s reinsurance payments to plans for the catastrophic spending of high-cost enrollees grew by an average annual rate of 19.5 percent. In 2014, Medicare’s reinsurance payments surpassed program spending for the LIS to become the single largest component of Part D spending.

We estimate that in 2014, nearly 70 percent of Medicare’s total program spending for Part D plans was on behalf of the 30 percent of Part D enrollees who receive the LIS. Specifically, in addition to the LIS itself (\$24.3 billion),

about 30 percent of Medicare’s direct-subsidy payments to plans (\$5.9 billion, or 30 percent of \$19.6 billion) and about 70 percent of individual reinsurance payments (\$19.5 billion, or 70 percent of \$27.8 billion) were for LIS enrollees. Disproportionate spending for this population reflects, in part, the policy goal of reducing the hurdle of OOP spending for low-income individuals. In addition, LIS enrollees tend, on average, to be in poorer health and use more medications than other enrollees.

In 2014, Part D program payments increased by nearly 15 percent over 2013 payments, much of that due to spending for new hepatitis C drugs (Boards of Trustees 2015). On a per capita basis, the Medicare Trustees observed faster

**TABLE
6-1**

Medicare’s reimbursement amounts for Part D

	Calendar year						Cumulative growth 2007-2014	Average annual growth rate 2007-2014
	2007	2009	2011	2012	2013	2014		
Reimbursement amount (in billions):								
Direct subsidy*	\$17.6	\$18.2	\$19.2	\$19.7	\$19.6	\$19.6	11.4%	1.5%
Reinsurance	8.0	10.1	13.7	15.5	19.2	27.8	247.5	19.5
Low-income subsidy	16.7	19.6	22.2	22.5	23.2	24.3	45.5	5.5
Retiree drug subsidy	3.9	3.9	3.6	3.0	1.8	1.6	-59.0	-12.0
Total	46.2	51.8	58.7	60.7	63.8	73.3	58.7	6.8

Note: Numbers above reflect reconciliation. Most enrollees paid premiums directly to plans, and those amounts are not included. On a cash basis, the Board of Trustees estimates that premiums paid by enrollees were \$4.1 billion in 2007, \$5.0 billion in 2008, \$6.1 billion in 2009, \$6.7 billion in 2010, \$7.3 billion in 2011, \$7.8 billion in 2012, \$9.3 billion in 2013, and \$10.5 billion in 2014. Components may not sum to stated totals due to rounding.

*Net of risk-sharing payments using Part D’s risk corridors.

Source: MedPAC analysis based on Table IV.B10 of the 2015 annual report of the Boards of Trustees of the Medicare trust funds.

than historical rates of growth in Part D spending in 2014, which they attributed to price increases for both brand-name and generic drugs. The Trustees expected even faster rates of increase in 2015 because of growth in the use of specialty drugs. Going forward, the Medicare Trustees project that between 2015 and 2024, per capita costs for Part D will grow by 5.6 percent per year. This rate is faster than projected per capita spending growth rates for Part A and Part B services because it reflects continued slowing in the use of generics and continued increases in the use and prices of specialty drugs. Because of the size of the baby-boom population entering Medicare, the Trustees project that aggregate program spending for Part D (net of enrollee premiums) will grow by 8.8 percent annually between 2015 and 2024, from \$76.9 billion to \$164.7 billion.

In each year since 2009, more than half of the FDA’s approvals of new drugs have been for specialty drugs (Long 2015). New specialty drugs are often launched at high prices. Specialty drugs in the development pipeline are concentrated in drug classes that treat conditions such as rheumatoid arthritis and inflammatory diseases, multiple sclerosis, cancer, and HIV, which are more prevalent within the Medicare population. Major pharmacy benefit managers (PBMs), insurers, and other organizations project that growth in prices of brand-name drugs and in the use of specialty drugs will continue to drive trends in spending (CVS Health 2016, Express Scripts Lab 2016, IMS Institute for Healthcare Informatics 2015).

High-priced specialty drugs pose a particular challenge for Part D. As more expensive therapies become available, larger numbers of beneficiaries could reach the catastrophic phase of benefit, when Medicare pays for 80 percent of the costs through individual reinsurance. Some of this trend has already happened with biologic products. Between 2009 and 2013, the share of high-cost enrollees who filled at least one prescription for a biologic product grew from 8 percent to 12 percent.⁸ During the same period, the share of gross Part D spending accounted for by biologic products grew from 6 percent to 10 percent.

The growing role of high-cost non-LIS enrollees

Recent growth in Part D program spending reflects two underlying trends. First, patent expirations on widely used brand-name drugs and plans’ use of tiered copayments have led to a dramatic shift toward use of generics. From 2007 through 2013, generic drugs’ share of all Part D prescriptions rose from 61 percent to 84 percent. Were this trend the only one, we would expect the shift toward generics to lead to lower growth in program spending—and though it has, in the sense that direct-subsidy payments and average enrollee premiums grew slowly between 2007 and 2014, other factors are changing that dynamic. Going forward, however, opportunities for further generic use are expected to diminish (Keehan et al. 2015).

**TABLE
6-2**

Growth in enrollment and spending for high-cost enrollees, 2007–2013

	2007	2010	2013	Average annual growth (in percent)	
				2007–2010	2010–2013
Number of enrollees (in millions)					
All Part D	26.1	29.7	37.8	4.4%	8.4%
High-cost enrollees					
LIS	1.9	2.0	2.1	1.3	3.0
Non-LIS	<u>0.4</u>	<u>0.4</u>	<u>0.7</u>	<u>-1.9</u>	<u>21.8</u>
Total high-cost enrollees	2.3	2.4	2.9	0.7	6.7
High-cost enrollees as a share of all Part D	8.8%	7.9%	7.6%	N/A	N/A
Gross spending (in billions of dollars)					
All Part D	\$62.1	\$77.6	\$103.7	7.7%	10.1%
High-cost enrollees					
LIS	19.7	25.5	33.4	8.9	9.5
Non-LIS	<u>4.3</u>	<u>5.7</u>	<u>14.9</u>	<u>9.9</u>	<u>37.9</u>
Total high-cost enrollees	24.0	31.2	48.4	9.1	15.8
High-cost enrollees as a share of all Part D	38.7%	40.1%	46.6%	N/A	N/A

Note: LIS (low-income subsidy), N/A (not applicable). Components may not sum to totals due to rounding. “High-cost enrollees” refers to enrollees with annual drug spending high enough to reach Part D’s out-of-pocket threshold. A beneficiary is classified as “LIS” if that individual received Part D’s LIS at some point during the year. Between 2010 and 2013, about half of the growth in the number of high-cost, non-LIS enrollees was due to growth in Part D employer group waiver plans (EGWPs). Largely because of changes in the Patient Protection and Affordable Care Act of 2010, employers that had previously provided primary drug coverage to their former workers and received Medicare’s retiree drug subsidy (RDS) instead set up Part D EGWPs for their retirees. Employers were motivated to make this shift because the law changed the tax treatment of the RDS and made the Part D benefit more generous through the phased closure of the coverage gap and the provision of brand discounts. (See the Commission’s March 2016 report to the Congress for more about enrollment growth in EGWPs.) The provision of a 50 percent discount on brand-name drugs from manufacturers and exclusion of that discount from Part D’s true out-of-pocket provision likely contributed to the growth in the number of high-cost, non-LIS enrollees among beneficiaries enrolled in EGWPs and other plans.

Source: MedPAC analysis of Medicare Part D prescription drug event data and MBD/CMS Medicare Entitlement file.

A second trend is that spending for high-cost enrollees—particularly those individuals who do not receive the LIS—has started to drive overall Part D program spending. From 2010 to 2013, the number of Part D enrollees increased as baby boomers began to retire and employers that had previously provided primary drug coverage to their former workers shifted their retirees to Part D by setting up employer group waiver plans. In addition, changes in the Patient Protection and Affordable Care Act of 2010 allowed manufacturers’ discounts on brand-name drugs to count toward an enrollee’s OOP spending in meeting the true OOP threshold, resulting in more beneficiaries reaching the OOP threshold. All of these factors have contributed to rapid growth (about 22 percent) in the number of non-LIS enrollees with high costs (Table 6-2). Meanwhile, between 2010 and 2013, gross spending for non-LIS enrollees with high costs grew from \$5.7 billion to \$14.9 billion—a nearly 38 percent increase. Between 2007 and 2010, the share of gross drug spending accounted for by high-cost enrollees

grew slowly from nearly 39 percent to slightly more than 40 percent and then jumped to nearly 47 percent by 2013.

Sharp increases in the average price of prescriptions filled by high-cost non-LIS enrollees have also contributed to growth in their gross spending. That growth may reflect increases in the prices of their medications, greater need for higher priced drugs, and other changes in the mix of medications they were prescribed. Between 2010 and 2013, the average price per standardized, 30-day prescription grew by 12.9 percent for high-cost non-LIS enrollees (Table 6-3, p. 170). By comparison, the average price per prescription for high-cost LIS enrollees grew by 4.3 percent and fell by 4.8 percent for Part D enrollees who did not reach the OOP threshold. The quantity of prescriptions used grew by a modest 2.2 percent across all Part D enrollees, but grew by just 0.2 percent for high-cost non-LIS enrollees. Overall, between 2010 and 2013, gross spending for all high-cost enrollees grew by 15.8 percent

**TABLE
6-3**

Growth in the number of high-cost enrollees and in the average price of prescriptions they use has driven much of Part D's spending growth in recent years

Breakdown of average annual spending growth, 2010-2013

Per enrollee amounts					
	Average price per prescription	Number of prescriptions	Spending	Numbers of enrollees	Gross spending
High-cost enrollees					
LIS	4.3%	1.9%	6.2%	3.0%	9.5%
Non-LIS	12.9	0.2	13.2	21.8	37.9
Total high-cost enrollees	7.2	1.2	8.5	6.7	15.8
Not high-cost enrollees	-4.8	2.7	-2.3	8.5	6.0
All Part D enrollees	-0.6	2.2	1.6	8.4	10.1

Note: LIS (low-income subsidy). "High-cost enrollees" refers to enrollees with annual drug spending high enough to reach Part D's out-of-pocket threshold. A beneficiary is classified as "LIS" if that individual received Part D's LIS at some point during the year. Numbers of prescriptions are standardized to a 30-day supply. Between 2010 and 2013, about half of the growth in the number of high-cost, non-LIS enrollees was due to growth in Part D employer group waiver plans (EGWPs). Largely because of changes in the Patient Protection and Affordable Care Act of 2010, employers that had previously provided primary drug coverage to their former workers and received Medicare's retiree drug subsidy (RDS) instead set up Part D EGWPs for their retirees. Employers were motivated to make this shift because the law changed the tax treatment of the RDS and made the Part D benefit more generous through the phased closure of the coverage gap and the provision of brand discounts. (See the Commission's March 2016 report to the Congress for more about enrollment growth in EGWPs.) The provision of a 50 percent discount on brand-name drugs from manufacturers, and exclusion of that discount from Part D's true out-of-pocket provision, likely contributed to the growth in the number of high-cost, non-LIS enrollees among beneficiaries enrolled in EGWPs and other plans.

Source: MedPAC analysis of Medicare Part D prescription drug event data and MBD/CMS Medicare Entitlement file.

compared with 6.0 percent growth in gross spending for enrollees who did not reach the OOP threshold.

Patterns of spending differ between high-cost enrollees with and without the LIS

In 2013, Part D had about 2.9 million high-cost enrollees (7.6 percent) (Table 6-4). About 2.1 million, or three-quarters of high-cost enrollees, received Part D's LIS, and 0.3 million resided in long-term care institutions.⁹ Because most LIS enrollees remained covered under traditional Medicare rather than under Medicare Advantage plans, 78 percent of high-cost enrollees were in PDPs (data not shown). High-cost enrollees were much more likely to be disabled beneficiaries (under age 65) and African American compared with all Part D enrollees.

In 2013, all Part D enrollees filled an average of 50 prescriptions during the year (or more than 4 per month) at an average price of \$54 per standardized 30-day prescription, for average annual spending of \$2,741. By comparison, high-cost enrollees filled an average of more than twice as many prescriptions (116, or 9.7 per month) at an average price per prescription that is more than two and

a half times higher (\$145), for average annual spending of \$16,914 per person.

Patterns of drug spending among high-cost enrollees vary depending on LIS status. High-cost LIS enrollees tend to fill a somewhat larger number of prescriptions (averaging 121, or 10.1 per month) compared with high-cost enrollees without the LIS (103 prescriptions, or about 8.6 per month). High-cost enrollees who resided in long-term care institutions (90 percent of whom received the LIS) had the highest use, at an annual average of 165 prescriptions (13.8 prescriptions per month).

High-cost enrollees without the LIS are more likely to use specialty drugs and biologics. For example, in 2013, of the 20 therapeutic classes that accounted for about 80 percent of spending by high-cost LIS enrollees, only four classes (e.g., antineoplastics and multiple sclerosis agents) were often associated with specialty tier drugs or biologic products. Spending for drugs in those four classes accounted for less than 8 percent of high-cost LIS enrollees' total spending compared with nearly 30 percent of spending by high-cost enrollees without the LIS (data not shown). This pattern is reflected in the higher average

**TABLE
6-4**

High-cost enrollees and their prescription use and spending, 2013

	High-cost enrollees				
	All Part D enrollees	LIS status			Long-term institutionalized
		All	LIS	Non-LIS	
Numbers of enrollees in millions	37.8	2.9	2.1	0.7	0.3
Percent of enrollees in category with high costs	N/A	7.6%	17.3%	2.8%	21.4%
As a percent of high-cost enrollees	N/A	100%	75%	25%	10%
Gender (in percent within category)					
Male	42%	40%	38%	46%	33%
Female	58	60	62	54	67
Age (in percent within category)					
Less than 65	20%	44%	54%	17%	19%
Between 65 and 80	57	40	33	63	38
80 and above	23	16	14	21	43
Race/ethnicity (in percent within category)					
White, non-Hispanic	74%	69%	63%	86%	75%
African American, non-Hispanic	11	15	18	5	15
Hispanic	10	11	12	5	7
Asian	3	4	5	1	2
Other	2	2	2	2	1
Total gross spending, in billions of dollars	\$103.7	\$48.4	\$33.4	\$14.9	\$3.5
Percent of total for high-cost enrollees	N/A	100%	69%	31%	7%
Total numbers of prescriptions, in millions	1,910	333	259	74	46
Percent of total for high-cost enrollees	N/A	100%	78%	22%	14%
Gross annual spending per enrollee, in dollars	\$2,741	\$16,914	\$15,599	\$20,847	\$12,730
Annual number of prescriptions per enrollee	50	116	121	103	165
Average price per prescription, in dollars	\$54	\$145	\$129	\$202	\$77
Average annual OOP spending per enrollee	\$365	\$773	\$127	\$2,706	\$192

Note: LIS (low-income subsidy), N/A (not applicable), OOP (out of pocket). Components may not sum to totals due to rounding. A beneficiary is classified as "LIS" if that individual received Part D's LIS at some point during the year. Individuals are classified as "long-term institutionalized" if they resided more than 90 days in an institution at some point during the year. Numbers of prescriptions are standardized to a 30-day supply.

Source: MedPAC analysis of Medicare Part D prescription drug event data and MBD/CMS Medicare Entitlement file.

spending by high-cost enrollees without the LIS: \$202 per prescription and \$20,847 per year compared with \$129 per prescription and \$15,599 per year for high-cost enrollees with the LIS (Table 6-4).

In 2013, high-cost LIS enrollees paid substantially lower cost sharing out of pocket than high-cost non-LIS enrollees. Average annual OOP cost-sharing amounts for high-cost LIS enrollees were \$127, compared with \$2,706 among non-LIS enrollees. One might expect average annual OOP spending for high-cost non-LIS enrollees to be higher than

\$4,750, which was Part D's OOP threshold in 2013. The average amount is lower primarily because those enrollees received credit that counted as OOP spending for the 50 percent discount provided by brand-name manufacturers in the coverage gap. By comparison, all Part D enrollees averaged \$365 in annual OOP cost sharing.

Generic use among high-cost enrollees

Patterns of Part D claims suggest that certain policy changes would allow plan sponsors to better manage

**TABLE
6-5**

Top 10 therapeutic classes by spending for high-cost enrollees who receive the low-income subsidy, 2013

Therapeutic classes	Gross spending (in billions of dollars)	Generic dispensing rate			
		High-cost LIS	High-cost non-LIS*	All non- high-cost	All Part D
Antipsychotics (neuroleptics)	\$4.1	58%	54%	93%	78%
Diabetic therapy	3.3	39	36	73	65
Antivirals	3.2	20	30	83	47
Asthma/COPD therapy agents	2.2	23	20	25	24
Analgesic, anti-inflammatory or antipyretic—non-narcotic	1.4	69	44	86	82
Analgesics—narcotic	1.4	90	85	97	96
Anticonvulsants	1.3	82	76	93	90
Antidepressants	1.2	80	76	94	91
Peptic ulcer therapy	1.2	68	71	89	85
Antihyperlipidemics	1.1	69	63	86	84
All therapeutic classes	33.4	71	67	86	84

Note: LIS (low-income subsidy), COPD (chronic obstructive pulmonary disease). Therapeutic classification based on the First DataBank Enhanced Therapeutic Classification System 1.0.

*For comparison, the top 10 therapeutic classes used by high-cost non-LIS enrollees in 2013 were antineoplastic—systemic enzyme inhibitors (\$1.6 billion); diabetic therapy (\$1.3 billion); antineoplastic—immunomodulators (\$1.1 billion); analgesic, anti-inflammatory or antipyretic—non-narcotic (\$1.0 billion); antivirals (\$0.8 billion); antihypertensive therapy agents (\$0.8 billion); asthma/COPD therapy agents (\$0.6 billion); multiple sclerosis agents (\$0.6 billion); antineoplastic—hormone/hormone antagonist agents (\$0.6 billion); and antihyperlipidemics (\$0.5 billion).

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

drug benefits for high-cost enrollees. Past research by the Commission has shown that plan sponsors are less successful at encouraging LIS enrollees to use generics. If plans were more successful, greater use of generics could reduce the number of individuals who reach the OOP threshold and moderate Medicare’s reinsurance payments to plans.

Consistent with our previous work, we find that having high costs is correlated with using more brand-name drugs (Medicare Payment Advisory Commission 2012). For example, in 2013, the average generic dispensing rate (GDR) among high-cost LIS enrollees was 71 percent, while the overall Part D average was 84 percent. High-cost non-LIS enrollees had a GDR that was even lower, at 67 percent (Table 6-5). Some of the difference reflects situations in which brand-name medications are the dominant standard of care for a therapeutic drug class, especially classes for newer specialty drugs. However, in other therapeutic classes such as diabetic therapy and

antihyperlipidemics, many of the drugs taken by high-cost enrollees are also used heavily by all Part D enrollees.

Across certain therapeutic classes, notable differences exist between high-cost enrollees and enrollees with lower drug spending. For example, among prescriptions for antipsychotics filled by high-cost enrollees in 2013—observed separately with and without the LIS—about 58 percent and 54 percent, respectively, were generics, compared with 93 percent for Part D enrollees who did not reach the OOP threshold (were not high cost) (Table 6-5). In the category of peptic ulcer therapies, the GDRs of high-cost enrollees with and without the LIS were 68 percent and 71 percent, respectively, compared with 89 percent among Part D enrollees with lower costs.

Multiple factors likely contribute to the higher or lower GDRs among groups of beneficiaries. For example, differences in health status may limit the opportunity for clinically appropriate therapeutic substitutions for some beneficiaries. For certain conditions, such as multiple sclerosis, rheumatoid arthritis, certain cancers, asthma,

and chronic obstructive pulmonary disease, prescribers predominantly treat patients with branded products. There can be geographic differences in prescribing behavior among physicians as well as differences between prescribers who are part of certain managed care settings and those who are not. Another factor may be the difference in financial incentives faced by LIS and non-LIS enrollees.

Patterns of Medicare payments and bidding incentives

In the Commission's June 2015 report to the Congress, we noted regular patterns in Medicare's reconciliation payments with plans (Medicare Payment Advisory Commission 2015a). First, many plan sponsors bid too low on the amount of benefit spending they expect above Part D's catastrophic threshold relative to their enrollees' actual catastrophic spending. Second, plan sponsors bid too high on benefit spending other than catastrophic benefits. Between 2009 and 2013, about three-fourths of parent organizations returned a portion of their prospective payments to Medicare through risk corridors. Actuaries interviewed by Commission staff suggested that there is significant uncertainty behind the assumptions they make when projecting drug spending for their bids. At the same time, we suggested that Part D's risk-sharing mechanisms could provide incentives to bid too low on catastrophic spending and too high on spending for the remainder of the Part D benefit. When plan sponsors underbid on the amount of individual reinsurance they will ultimately receive, Medicare pays an overall Part D subsidy higher than the 74.5 percent specified in law, which helps plan sponsors keep their premiums low. We estimate this higher subsidy occurred in most years from 2007 through 2014.

In their 2015 report, the Medicare Trustees projected that, because of higher than anticipated spending on new hepatitis C therapies in 2014, most plans would receive risk-corridor payments from Medicare in 2015 rather than return overpayments (Boards of Trustees 2015). However, the projection was not fully accurate. For benefits delivered in 2014, 81 percent of plan sponsors received additional individual reinsurance payments from Medicare at reconciliation, much of which was due to hepatitis C spending. Ultimately, however, 62 percent of Part D plan sponsors made risk-corridor payments to Medicare (rather than receiving payments from Medicare) for 2014 benefits. In aggregate, those payments totaled less than \$100 million, much lower than risk-corridor payments from plan sponsors to Medicare in recent years.

Potential improvements to Part D

The Commission recommends improvements to the Part D program that are interrelated changes. Sponsors of Part D plans would shoulder more insurance risk but would also have greater flexibility to use formulary tools. The Commission's recommendations would modify what would count toward Part D's OOP spending threshold, would provide greater protection to all non-LIS enrollees through a real OOP cap, and would increase financial incentives for enrollees who receive the LIS to use lower cost drugs and biologics. At the same time, these changes would need to be accompanied by a recalibrated risk adjustment system, regular monitoring of beneficiary access, and well-functioning appeals and grievance procedures.

The net impact of the Commission's recommendations restrains overall drug costs and makes the benefit more affordable for beneficiaries and taxpayers in the long run. The recommendations enhance the Part D benefit so that the program would provide real insurance protection against catastrophic OOP spending. However, the recommendations would also expose some beneficiaries to higher cost sharing in the coverage gap. To the extent that the adoption of this combined set of recommendations results in net program savings, the Congress could consider enhancing protections for non-LIS beneficiaries facing high cost-sharing burdens.

Changes related to Part D's OOP spending threshold

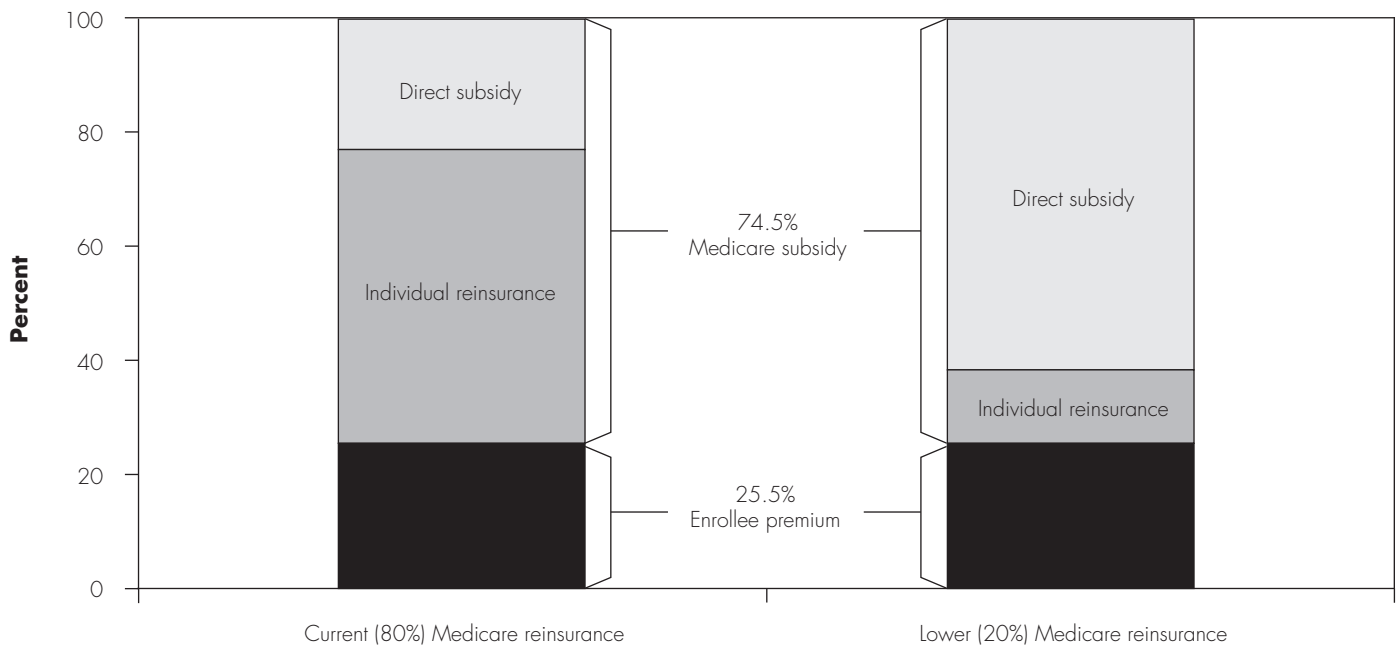
The Commission recommends changes that would reduce Medicare's individual reinsurance, discontinue counting brand-name discounts as enrollees' own "true OOP" spending, and eliminate enrollee cost sharing above Part D's OOP threshold.

A larger portion of Medicare's subsidy through capitated payments

One step toward better managing Part D spending would be for Medicare to pay a larger portion of its prescription drug subsidy through capitated payments. Currently, Medicare subsidizes 74.5 percent of the expected cost of basic drug benefits, with enrollees paying the remainder through premiums. Medicare's subsidy share is made up of two components: monthly direct-subsidy payments and expected individual reinsurance payments to plans, in which Medicare pays 80 percent of catastrophic spending. Under the recommendation (described on pp. 183–184),

FIGURE 6-5

Recommended change in how Medicare provides its 74.5 percent subsidy to Part D plans



Note: Medicare subsidizes about 74.5 percent of the cost of basic Part D benefits through a combination of monthly capitated payments and individual reinsurance payments to plans. Enrollees pay the remainder (about 25.5 percent) in premiums. As one component of Medicare's subsidy, the program currently pays 80 percent of each high-cost enrollee's spending above Part D's out-of-pocket threshold as individual reinsurance. Under the recommendation, Medicare would lower its reinsurance to 20 percent of catastrophic spending but also increase capitated payments to keep the combined Medicare subsidy at 74.5 percent. Medicare payments and enrollee premium shown assume no behavioral changes.

Medicare would keep its subsidy of Part D at 74.5 percent of basic benefits, but the structure of individual reinsurance would be changed so that plans included more of the costs of catastrophic spending in their covered benefits. In other words, Medicare would provide more of the 74.5 percent subsidy through capitated payments and less of the subsidy through open-ended individual reinsurance.

Discussions with plan executives and academic economists suggest that the current structure of Medicare's reinsurance subsidy takes away the urgency for sponsors to manage prescription use among high-cost enrollees. One commenter pointed out that the rebates sponsors receive from manufacturers for brand-name drugs dispensed to enrollees who reach Part D's OOP threshold (including rebates in the coverage-gap phase) can more than offset plans' 15 percent share of payments for spending that exceeds the OOP threshold. Requiring plans to pay a share

larger than 15 percent would provide greater incentive for sponsors to negotiate larger rebates with manufacturers or design formularies in ways that encourage greater use of lower cost drugs.

Under the Commission's recommendation, Medicare's overall subsidy would remain at 74.5 percent, but the share of that subsidy provided through individual reinsurance would be reduced over a transition period, and the dollar amount of capitated direct-subsidy payments would increase (Figure 6-5). (Medicare's reinsurance subsidy, currently 80 percent of catastrophic spending, is notionally different from the program's overall 74.5 percent subsidy. Medicare pays reinsurance only for individuals who reach the OOP threshold, and the reinsurance subsidy is one component of the overall 74.5 percent subsidy.) At the end of the transition period and after implementation of a real catastrophic cap (described in the section about limiting enrollee cost sharing above the OOP threshold), ultimately

plan sponsors would be at risk for 80 percent of the spending above the OOP limit rather than 15 percent as they are today. Medicare would pay 20 percent reinsurance instead of the current 80 percent. The Commission's recommendation would retain 20 percent reinsurance through Medicare as a complement to risk adjustment, to protect plans against the consequences of an individual enrollee's unpredictably high benefit spending. The recommendation would also retain Part D's risk corridors as currently structured to provide sponsors with overall protection at the plan level.

Because the overall subsidy rate of 74.5 percent would remain the same, the recommendation might not affect enrollee premiums—assuming no behavioral changes. However, because more of Medicare's subsidy would take the form of a capitated payment rather than open-ended reinsurance, plan sponsors would be at risk for more of covered benefits than they are today. Assuming greater risk for high-spending enrollees would likely require plans to reevaluate their overall bidding and operational strategy. For example, plan sponsors might bargain more aggressively with drug manufacturers over rebates and prices. This approach would also give sponsors more incentive to move high-cost enrollees to lower cost drugs (such as generics) when available, or to encourage them to use lower cost pharmacies.

One question to consider relates to the growing influence of higher priced specialty drugs. Even if Medicare required plan sponsors to bear more risk in Part D, would sponsors have sufficient market power to negotiate larger price discounts with pharmaceutical manufacturers? For some drug therapies that are the first in a class with a new mechanism of action or breakthrough therapies, and those with few or limited substitutes, the answer may be no. For these situations, Part D's risk adjusters would be recalibrated to reflect the higher spending of enrollees who fill prescriptions for those drugs, and the program's risk corridors would protect sponsors from unexpectedly large losses at the plan level. However, for other drug therapies, even the prospect of potential competitors in the development pipeline can give plan sponsors and their pharmacy benefit managers bargaining leverage with manufacturers. For example, in our discussions with plan actuaries, some noted that they were able to obtain rebates on Sovaldi even when it was the only hepatitis C treatment of its kind on the market because of the leverage provided by other therapies that were about to receive FDA approval.

Other behavioral changes could result in higher plan costs for providing the benefit. For example, because they would bear more risk, plan sponsors might build in a larger risk premium (that is, compensation required by insurers for bearing a given level of risk) or decide to purchase private reinsurance to protect themselves from large losses (called stop-loss coverage). The cost of any risk premium or private reinsurance would be reflected in a higher bid. However, plans that purchased private reinsurance could be subject to the practice of "lasering," in which reinsurers do not cover (or provide less coverage for) plan enrollees with predictably high levels of spending (see text box about lasering, pp. 176–177).

How much reinsurance should Medicare provide? A key consideration is the level of uncertainty inherent in predicting catastrophic spending. In 2013, among the 2.9 million beneficiaries who reached Part D's OOP threshold, 1.8 million, or 65 percent, also had high costs in 2012 (Table 6-6, p. 178). In 2013, those 1.8 million individuals accounted for about 70 percent of gross Part D spending and 76 percent of the gross spending above the OOP threshold.

Plan sponsors often use predictive modeling that incorporates information about enrollees' diagnoses and past claims to estimate future spending. Given the predictability of drug spending, perhaps a larger uncertainty for insurers is how much catastrophic spending would be incurred by enrollees without a history of high costs. If the goal of Medicare's reinsurance is to protect plan sponsors from unpredictably high drug spending, then providing sponsors with reinsurance substantially lower than 80 percent would appear to still offer adequate protection. At the same time, it would be prudent to phase down Medicare's reinsurance subsidy over a few years so that plan sponsors could adjust to higher levels of risk and CMS could recalibrate Part D's risk adjusters.

Under the recommendations, Part D's risk adjusters would become more important as a tool for counterbalancing plan incentives for selection, and CMS would need to take steps to recalibrate the risk adjustment system. Recalibrating Part D's risk adjusters to reflect the higher plan liability is notionally similar to the adjustments CMS has made to the RxHCC model since 2010 to reflect the phased closure of Part D's coverage gap. Since 2011, CMS has had to adjust the expenditure data used for estimating the model coefficients to reflect a different benefit structure as the phaseout of the coverage gap increases the share of drug spending for which plans

Persistence of high drug costs and the practice of “lasering” in private reinsurance

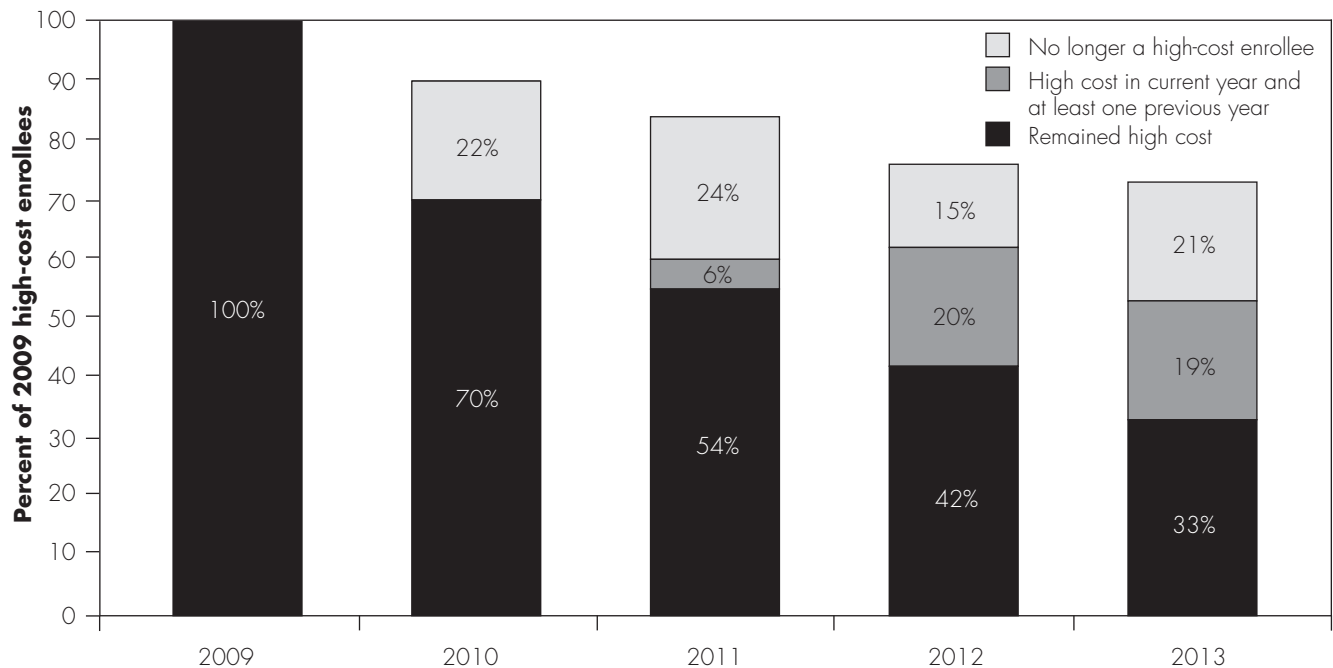
Medicare beneficiaries often have multiple chronic conditions treated with medications, and their drug-spending patterns can be highly predictable (Boccuti and Moon 2003). For this reason, plan sponsors and reinsurers may have particularly strong information with which to identify individuals who have persistently high costs.

To understand the persistence of high costs in Part D, we examined the spending patterns of enrollees who reached the out-of-pocket (OOP) threshold between 2009 and 2013 (Figure 6-6). We found that Part D spending for high-cost individuals tended to persist over time. By the end of the five-year period, more than one-quarter of the original 2009 cohort had died.

(continued next page)

FIGURE 6-6

Persistence of high spending and mortality in the cohort of enrollees who reached Part D’s out-of-pocket threshold in 2009



Note: “High-cost enrollees” refers to enrollees with annual drug spending high enough to reach Part D’s out-of-pocket threshold. The denominator of the percentage is the number of individuals who reached the out-of-pocket threshold in 2009. The declining height of the bars reflects enrollees who died. “Remained high cost” means the individual had high costs in each year. Shares of enrollees who remained high cost or were “high cost in current year and at least one previous year” would be higher if decedents were excluded from the calculation.

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

are responsible. CMS could similarly adjust upward the portion of claims for which plans would be liable if there were lower reinsurance. In addition, because spending in the catastrophic phase of the benefit is large and likely concentrated among beneficiaries with certain conditions, CMS would need to review condition categories.

Even though Medicare would continue to risk adjust payments and retain risk corridors, plan sponsors may include a larger risk premium in their bids or purchase private reinsurance. However, most Part D enrollees are in plans sponsored by large insurers. By virtue of having larger risk pools, these plan sponsors would likely be able

Persistence of high drug costs and the practice of “lasering” in private reinsurance (cont.)

Just over 20 percent of the 2009 cohort did not reach the OOP threshold in 2013 (“no longer a high-cost enrollee”), about 19 percent incurred high spending in two to four of the years, and more than 30 percent incurred high spending in all five years (“remained high cost”). The shares of individuals with persistently high spending would be larger if decedents were omitted from the calculations.

When a beneficiary has predictably high drug spending, private reinsurance companies may require modifications to stop-loss agreements with plan sponsors. For example, the reinsurer might exclude the beneficiary from future coverage. Alternatively, the reinsurer might agree to cover the beneficiary only at a higher stop-loss amount. Such modifications apply only to the individual enrollee; that is, the lower stop-loss threshold continues to apply for the rest of the covered

population. This practice of pinpointing high-risk individuals is known as “lasering.” Reinsurers’ rationale behind lasering is that, because some enrollees have predictably higher spending, the sponsor should build those costs into the plan’s premiums rather than rely on reinsurance to cover the higher expected benefit costs.

Conceptually, the same lasering notion should apply in Part D, but the current structure of Medicare’s individual reinsurance payments carves out predictable costs of high-cost enrollees from plan bids. If Medicare paid plans a lower share of individual reinsurance, then plans with higher concentrations of high-cost enrollees would have higher bids. It is very important for CMS to recalibrate the prescription drug hierarchical condition category risk adjustment system to reflect plans’ higher benefit spending and to discourage plan sponsors from avoiding such beneficiaries. ■

to shoulder more of their enrollees’ insurance risk. In 2013, some parent organizations offered only PDPs, others offered only MA–PDs, but many offered both. Among the 63 parent organizations that sponsored PDPs, only about 1 percent of Part D enrollees were in PDPs operated by parent organizations that had enrollment totaling less than 30,000. Conversely, 95 percent of PDP enrollees were in plans offered by parent organizations with enrollment totaling 125,000 or more. By comparison, larger numbers of sponsors had MA–PDs with smaller enrollment: 134 parent organizations had 5,000 or fewer MA–PD enrollees, and 57 parent organizations had between 5,000 and 30,000 enrollees. Nonetheless, total enrollment in MA–PDs was still fairly concentrated: 71 percent of enrollees were in plans sponsored by parent organizations with MA–PD enrollment totaling 125,000 or more.

Large plan sponsors also participate in other major insurance markets, covering, for example, MA plans’ medical benefits, employer health plans, and the health insurance exchanges. In the case of MA, Medicare does not provide any individual reinsurance, and some plan sponsors already purchase private reinsurance. In interviews, private reinsurers suggested that existing

reinsurance contracts with MA plans could be modified to include drug spending and medical benefits. Consulting actuaries also suggested that large insurance companies would have sufficient capital and cash flow on hand to set up systems of cross-subsidies among their business lines to reinsure themselves. However, smaller plan sponsors would likely need to purchase private reinsurance, which could affect their decision to enter or exit the Part D market.¹⁰

Manufacturers’ discounts on brand-name drugs and Part D’s OOP threshold

Although Part D’s defined standard benefit currently includes a coverage gap, in 2020, the Part D benefit will become more generous so that drug spending now in the coverage gap will have the same 25 percent cost sharing that applies to the benefit’s initial coverage phase. From 2006 to 2010, non-LIS enrollees exceeding the initial coverage limit were responsible for paying the full price of covered drugs up to the annual OOP threshold (Figure 6-7, p. 179). In 2016, the coverage gap has been partially phased out. Non-LIS enrollees in the coverage gap pay 45 percent of their brand-name drug costs and 58 percent of

**TABLE
6-6**

More than three-quarters of Part D's catastrophic spending in 2013 was for enrollees who also had high costs in 2012

	Enrollees		Total gross spending		Gross spending above Part D's out-of-pocket limit	
	In millions	In percent	In billions	In percent	In billions	In percent
Enrollees with high costs in 2013						
High cost in 2012	1.8	65%	\$34.0	70%	\$21.1	76%
Not high cost in 2012	1.0	35	14.4	30	6.6	24
Total	2.9	100	48.4	100	27.7	100

Note: Components may not sum to totals due to rounding.

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

their generic drug costs, while the Part D benefit covers 5 percent of their brand-name drug costs and 42 percent of their generic drug costs. Manufacturers provide a 50 percent discount that covers the remaining costs for brand-name drugs. In 2020 and thereafter, the Part D benefit will cover 25 percent of covered brand-name drug spending in what is now the coverage gap, the enrollee will pay 25 percent cost sharing, and brand manufacturers will continue to provide a 50 percent discount on price.

Generally, only cost sharing paid by the enrollee counts toward the OOP threshold. However, under PPACA, brand-name discounts are also counted toward the OOP spending threshold of non-LIS enrollees.¹¹ By comparison, Part D does not count most other sources of supplemental drug coverage toward an enrollee's OOP threshold ("true OOP" provision).¹² For example, for a plan enrollee with retiree drug coverage or enhanced benefits that wrap around his or her Part D plan benefit (e.g., paying the deductible or covering some cost sharing in the coverage gap), Medicare counts only the beneficiary's own OOP spending toward the threshold. This feature of the benefit ensures that, if a beneficiary has supplemental coverage, no part of that supplemental benefit would be replaced or subsidized by Part D. Under PPACA, manufacturer discounts for brand-name drugs are exempted from this "true OOP" provision so that those amounts are treated as though the beneficiary had paid them.

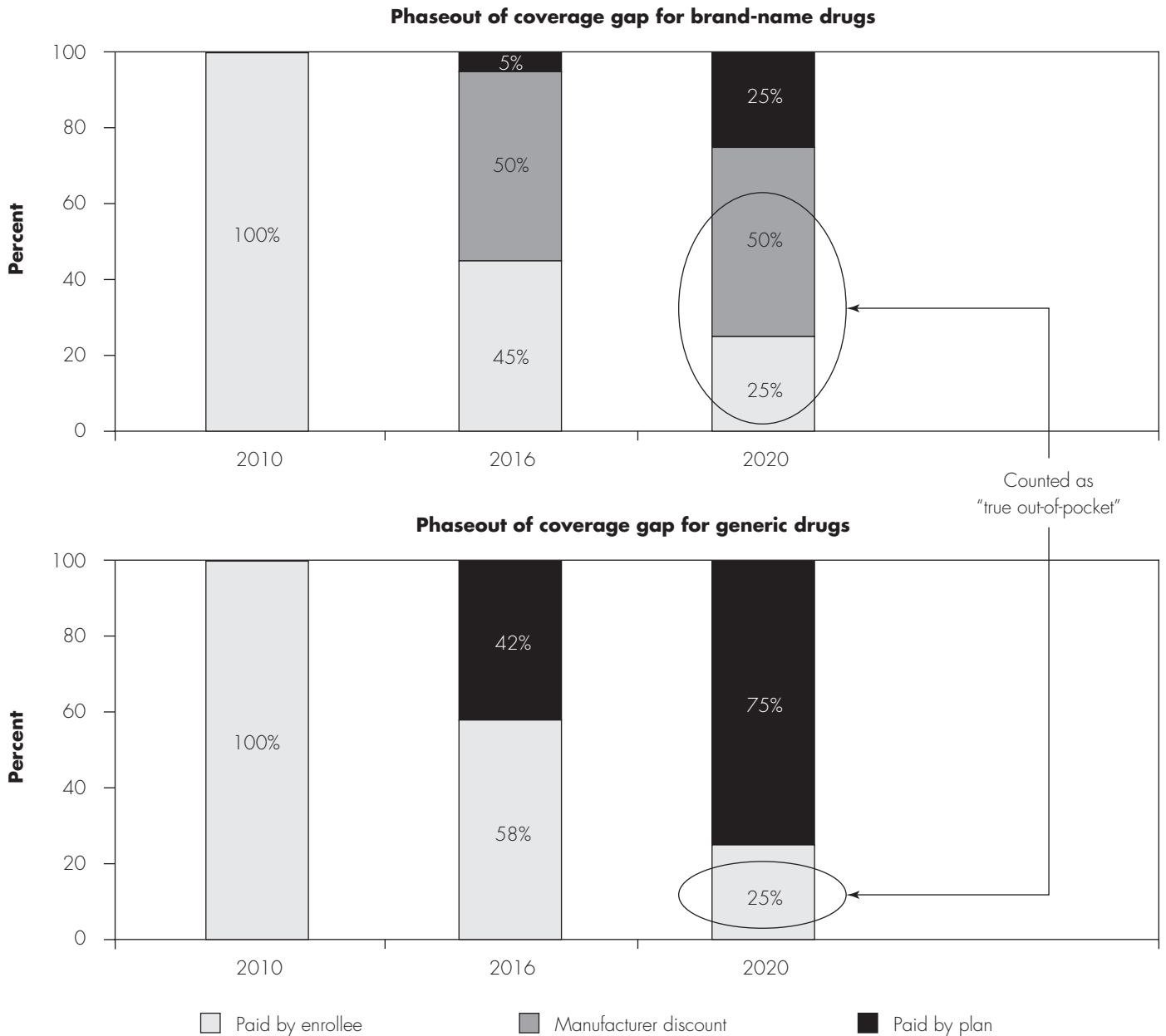
Brand-name discounts lower relative prices for brand-name drugs. For therapeutic classes in which an enrollee has a choice of both brand-name and generic alternatives,

the policy makes brand-name drugs appear less expensive than they would otherwise.¹³ Because manufacturers' discounts are counted as the enrollee's own spending, the exemption of discounts from the true OOP provision allows the enrollee who fills brand-name drugs to reach the OOP threshold more quickly (i.e., at a lower level of drug spending) (see text box on beneficiary spending at the OOP threshold, p. 180). In turn, this exemption quickens the pace at which Medicare begins paying for 80 percent of enrollees' benefits through reinsurance. Meanwhile, plan sponsors may not be as motivated to encourage use of generics as much as they might otherwise because the plan's responsibility for benefit spending is lowered by the brand discount and the plan sponsor receives rebates for brand-name drugs from manufacturers. Ultimately, program spending is greater because Medicare pays for 80 percent of spending above the OOP threshold. (Plan incentives and effects on program spending could change significantly under the Commission's recommendation to reduce Medicare's reinsurance and increase plan risk for catastrophic benefits.)

In 2010, about 400,000 non-LIS enrollees reached the OOP threshold. After PPACA was enacted, that number grew to about 700,000 by 2013—more than 80 percent higher. Among those 700,000 enrollees, total drug spending averaged \$20,847. Of that total, these enrollees paid average cost sharing of \$2,706, and less than 10 percent paid \$4,750 from their OOP spending alone (\$4,750 was Part D's OOP threshold in 2013). Under the current approach, from the enrollees' perspective, manufacturer discounts may have an effect similar to copayment coupons offered by manufacturers of brand-

FIGURE 6-7

Brand-name drugs are treated differently from generics in the coverage gap



Source: MedPAC based on Kaiser Family Foundation 2010.

name drugs; that is, by replacing their cost-sharing liability, the discounts may provide greater incentive to use brand-name drugs when lower cost options are available (Maggs and Kesselheim 2014). This discrepancy could be mitigated in 2020, when the same 25 percent coinsurance will apply to both brand-name drugs and generics. If manufacturer discounts had not been counted toward the

OOP threshold, most individuals likely would not have reached Part D’s catastrophic phase as quickly, and some would not have reached it at all. Meanwhile, enrollees who used generic medications alone would need to pay more out of their own pocket before reaching the OOP threshold, since they would not receive manufacturers’ discounts.

Individual enrollees' level of drug spending at the OOP threshold depends on mix of brand-name and generic prescriptions

In Part D's coverage gap, the share of drug spending counted toward the out-of-pocket (OOP) threshold differs between brand-name and generic drugs. For example, consider two beneficiaries who, by the middle of 2016, have already accumulated \$3,310 in drug spending, which marks the start of the coverage gap. Here we consider each beneficiary's next \$100 of spending for either a generic or brand-name prescription, but bear in mind that in 2013, the average retail price of a brand-name prescription under Part D was 13 times more expensive than a generic (\$242 per standardized 30-day supply of a brand-name drug compared with \$18 for a generic). The first beneficiary pays \$100 toward a generic prescription. Her plan covers 42 percent (\$42); she pays 58 percent and receives \$58 credit toward her true OOP threshold. A second beneficiary also pays \$100, but toward a brand-name prescription. The pharmacy reduces the price by \$50 because of the brand-name discount, the

enrollee pays 45 percent (\$45), and his plan pays 5 percent (\$5). Under current policy, the second enrollee is credited with \$95 of true OOP spending—\$45 out of his own pocket and \$50 from the brand manufacturer. Even though both beneficiaries spent the same amount (\$100), the second enrollee is \$37 closer to reaching his \$4,850 OOP threshold (\$95 minus \$58) than the first enrollee because he used a brand-name drug.

This example shows how spending at the OOP threshold varies across individuals depending on the mix of brand-name and generic drugs they use. Enrollees are credited with relatively more OOP spending when they use brand-name drugs than when they use generics. A beneficiary using only brand-name drugs would reach Part D's \$4,850 OOP threshold at \$7,260 in total spending. By comparison, an enrollee who used only generic drugs would reach the OOP threshold at \$9,780 in total spending. ■

Limit enrollee cost sharing above the OOP threshold

Prices of some specialty drugs have reached levels around \$100,000 or more per regimen before rebates. Plans often require enrollees to pay 25 percent to 33 percent cost sharing for these drugs and higher cost sharing in the coverage gap until the patient reaches Part D's OOP threshold, after which the patient pays 5 percent of the price. Part D enrollees are not permitted to use manufacturers' coupons to reduce their cost sharing because such arrangements are considered an inducement.¹⁴ Beneficiaries who do not receive the LIS but who do have a condition for which specialty drugs are prescribed can face significant financial challenges to pay cost sharing before they reach Part D's OOP limit. Even after they reach that threshold, 5 percent of the price of each prescription can be substantial. For some specialty drugs, an enrollee could potentially pay one-third to more than half of all their out-of-pocket costs above Part D's OOP threshold (Hoadley et al. 2015).

To analyze the extent of this burden, we examined the average cost-sharing amounts paid out of pocket by non-

LIS enrollees once they entered the catastrophic phase of the benefit. In 2013, OOP spending averaged \$2,706 among the roughly 700,000 non-LIS enrollees who reached the OOP threshold (Table 6-7). That amount is less than the \$4,750 threshold amount in Part D's benefit structure for 2013 because manufacturer discounts averaging \$2,293 were counted as true OOP spending. Of the \$2,706 paid by the enrollee, about \$814 (30 percent) was for cost sharing paid in the catastrophic phase of the benefit. However, many beneficiaries paid less.

Three-quarters of the 700,000 enrollees paid \$664 or less in cost sharing above the OOP threshold (Table 6-7). Those enrollees reached Part D's OOP threshold at an average of \$8,966 in total drug spending. Of that amount, manufacturers' discounts contributed an average of \$2,372 and enrollees paid an average of \$1,983 themselves, or 22 percent of the total spending below the OOP threshold. Above the OOP threshold, those enrollees paid on average an additional \$221, or 10 percent of their combined OOP spending. The effective average coinsurance rate in the benefit's catastrophic phase was 4 percent for this group of enrollees. Altogether, in 2013, these high-cost enrollees

**TABLE
6-7**

Average drug spending and cost sharing paid OOP among non-LIS enrollees who incurred high costs in 2013

	Benefit phases			
	All benefit phases	Below OOP threshold	Above OOP threshold	Percent above OOP threshold
All enrollees				
Total drug spending	\$20,847	\$8,647	\$12,200	59%
Cost sharing paid OOP	2,706	1,892	814	30
Manufacturer discounts	2,293	2,293	N/A	N/A
Percent of drug spending paid OOP	13%	22%	7%	
Enrollees with OOP costs in catastrophic phase at or below 75th percentile (\$664)				
Total drug spending	\$14,372	\$8,966	\$5,406	38%
Cost sharing paid OOP	2,204	1,983	221	10
Manufacturer discounts	2,372	2,372	N/A	N/A
Percent of drug spending paid OOP	15%	22%	4%	
Enrollees with OOP costs in catastrophic phase above 75th percentile (\$664)				
Total drug spending	\$40,273	\$7,692	\$32,581	81%
Cost sharing paid OOP	4,213	1,618	2,596	62
Manufacturer discounts	2,054	2,054	N/A	N/A
Percent of drug spending paid OOP	10%	21%	8%	

Note: OOP (out-of-pocket), LIS (low-income subsidy), N/A (not applicable).

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

spent \$14,372 on drugs, about 16 percent of which paid for generic drugs (data not shown).

The remaining 25 percent of high-cost, non-LIS enrollees had OOP spending greater than \$664 in 2013. Those enrollees reached their OOP threshold at an average of \$7,692 in drug spending, but their overall drug spending averaged more than \$40,000 so that 81 percent of their spending was incurred in the benefit's catastrophic phase. On average, about 8 percent of their spending paid for generic drugs (data not shown). Manufacturers' discounts for brand-name drugs averaged \$2,054, and enrollees paid an average of \$1,618 themselves, or 21 percent. Because so much of their total drug spending was in the catastrophic phase of the benefit, those enrollees paid much higher amounts themselves, averaging \$2,596,

which accounted for 62 percent of their total OOP spending (\$4,213).

There are pros and cons associated with providing more complete OOP protection than Part D provides today. High amounts of cost sharing may discourage beneficiaries from using appropriate therapies. Further, the current benefit structure appears to provide greater OOP protection to individuals with mid-to-low drug spending, with no limit on cost sharing for those with the highest spending. Enrollees in MA plans already have a hard OOP limit on spending for their Part A and Part B benefits. Some analysts contend that prescribers (more than enrollees) establish patterns of prescription therapy long before the beneficiary reaches the OOP threshold, and cost sharing above the cap would be punitive rather than provide incentives to use lower cost medicines. However, it is not

always clear that some high-priced drug therapies improve clinical outcomes for patients. The absence of cost sharing may result in higher necessary and unnecessary use of both high-priced and other therapies.

Potential effects of changes related to the OOP threshold

The Commission recommends three changes related to Part D's OOP threshold: (1) reduce Medicare's individual reinsurance from 80 percent to 20 percent; (2) exclude manufacturer discounts on brand-name drugs from counting toward enrollees' OOP spending; and (3) provide Part D enrollees with an absolute, or "hard," OOP cap once they reach the catastrophic threshold.

Analyzing the effects of these policy changes is challenging for several reasons. Part D's defined benefit structure has multiple cost-sharing phases, and the level of drug spending needed to reach the catastrophic phase of the benefit varies across individuals depending on their mix of brand-name and generic drugs. Part D plans use different benefit designs, sometimes with enhanced (supplemental) benefits. For example, it appears that enrollees with high spending may seek out enhanced benefits. Claims data show that among the non-LIS enrollees with high costs in 2013, enhanced benefits through Part D plans covered an average of \$540 of their drug spending.

The gradual phaseout of the coverage gap means that Part D's benefit will become more generous each year until 2020. In turn, that new benefit structure could affect the share of Part D enrollees who reach the OOP cap. However, we did not try to model effects of the policy changes in 2020 because of the large amount of uncertainty in the future distribution of drug spending. Projecting future drug spending would involve predicting the entry dates of new drugs and biologics into the market and the prices at which they would be launched, the degree to which physicians would prescribe new drugs to patients, price trends for drugs already on the market, plans' success at encouraging use of lower cost drugs, and enrollment levels in Part D, among other factors.

Combined effects of applying the true OOP provision to manufacturer discounts and eliminating cost sharing on spending above the OOP threshold If the true OOP provision had applied to manufacturer discounts in 2013, then beneficiaries would have had to spend higher amounts themselves to reach the OOP threshold because manufacturer discounts would no longer have been

counted as the enrollee's OOP spending. At the same time, eliminating cost sharing above the OOP threshold would provide better protection to all enrollees in the sense that Part D would offer true insurance. Based on our analysis of the Part D claims data for 2013, we estimate the two policy changes would have the following combined effects:¹⁵

- At the 2013 rates of coinsurance, on average, all of the 700,000 non-LIS enrollees would remain in the coverage gap longer and would each pay about \$1,000 more in cost sharing.
- Manufacturers of brand-name drugs would pay an average additional \$1,000 per enrollee because they would be offering brand discounts throughout a longer coverage-gap phase.
- About half of the 700,000 non-LIS enrollees who reached the OOP threshold in 2013 would no longer reach that threshold.
- The remaining 350,000 non-LIS enrollees would still have OOP spending high enough to reach the benefit's catastrophic phase, but the hard OOP cap would provide an upper limit on their spending. On average, individuals who reached the hard OOP cap would pay about \$1,000 less in catastrophic cost sharing. Combining the hard OOP cap with the change in the treatment of manufacturer discounts would result in better financial protection for individuals with the highest costs.
- Because fewer enrollees would reach the OOP threshold, Medicare's subsidy payments for spending above the threshold would also be lower. In 2013, that reduction would have totaled about \$1 billion.
- Part D enrollees would experience little or no change to their monthly premiums. On its own, the exclusion of manufacturer discounts from the true OOP provision would lower premiums slightly (less than \$1 per month) because there would be fewer enrollees reaching the OOP threshold. Likewise, on its own, a hard OOP cap would lead to slightly higher monthly premiums for all enrollees (also less than \$1) because the Part D benefit would be more generous. Because these premium changes are of about the same magnitude, there would be little or no net change in monthly premiums paid by Part D enrollees.
- From Medicare's perspective, the increase in the benefit costs resulting from the expanded benefit

would be offset almost entirely by reductions in the program's subsidy payments for low-income cost sharing. In other words, Medicare had formerly paid for the 5 percent cost sharing on behalf of LIS enrollees; however, under the proposed change, that amount would now be part of Part D's basic benefit.

Estimated effects and future uncertainties A caution about estimating the effects of proposed changes is that many factors could influence the outcome. For 2013, the number of non-LIS enrollees who reached the OOP threshold was still fairly small—about 700,000 individuals—but their numbers are growing (Medicare Payment Advisory Commission 2016). In addition, the Medicare Trustees expect that use of and prices for biologics and specialty drugs will increase faster than other components of health care spending (Boards of Trustees 2015). Those factors could push the costs of a hard cap on OOP spending considerably higher. Scheduled changes to Part D's benefit structure and other changes to the underlying distribution of drug spending will also factor into the effects of changes to the true OOP provision by 2020.

The effects described above assume no behavioral change on the part of plan sponsors or enrollees, but behavioral changes would be likely. For example, eliminating all cost sharing above Part D's OOP threshold could lead some enrollees to fill more prescriptions. Also, the exclusion of the manufacturer discount from the true OOP spending could affect beneficiaries' decisions about choosing generic alternatives when available by changing the relative price of brand-name and generic drugs.

Finally, to the extent that the policy increases the amount of discounts paid by brand manufacturers, it may result in lower manufacturer rebates. At the same time, because plan sponsors would be assuming greater risk under the policy, they may negotiate more aggressively with drug manufacturers over prices and rebates. Thus, it is not clear how the increase in manufacturer discounts would affect the size of manufacturer rebates that plan sponsors would be able to negotiate under the policy.

RECOMMENDATION 6-1

The Commission's first recommendation has three parts. The first would provide more of Medicare's subsidies through capitated payments rather than through individual reinsurance. Under the second part, manufacturer discounts on brand-name drugs would be excluded from true OOP spending. Under the third part, Part D would provide more complete insurance protection against

high OOP spending. Specifically, the Commission recommends:

The Congress should change Part D to:

- **transition Medicare's individual reinsurance subsidy from 80 percent to 20 percent while maintaining Medicare's overall 74.5 percent subsidy of basic benefits,**
- **exclude manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending, and**
- **eliminate enrollee cost sharing above the out-of-pocket threshold.**

RATIONALE 6-1

Since Part D began, individual reinsurance payments rather than capitated payments have assumed a growing share of Medicare's subsidy of enrollees' Part D spending, and the taxpayers' share of the benefit costs has been somewhat greater than the 74.5 percent specified in law. The original intent behind Part D's market-based approach was for private plans to negotiate with pharmaceutical manufacturers and pharmacies over drug prices and to use formularies and differential cost sharing to encourage enrollees to use lower cost medicines. However, the current structure of Medicare's reinsurance subsidy removes the urgency for plan sponsors to manage prescription use of high-cost enrollees and negotiate lower drug prices. The recommendation would give plan sponsors stronger incentives to manage overall benefit spending while retaining the risk protection afforded to plan sponsors through risk corridors. The reduction of Medicare's rate of reinsurance payments over a transition period and the retention of risk corridors would limit the financial impact of the policy on any individual Part D plan sponsor.

The second part of the recommendation relates to the types of expenditures that count toward Part D's OOP threshold for enrollees who do not receive the LIS. (Because LIS enrollees pay comparatively low cost-sharing amounts, these enrollees' OOP spending does not reach Part D's OOP threshold.) Under changes enacted in 2010, pharmaceutical manufacturers of brand-name drugs must provide a 50 percent discount to enrollees beginning at the coverage-gap phase of the benefit, and those discounts are credited toward an enrollees' OOP spending threshold, as if the enrollee paid that amount out of pocket. That policy both lowers the price of brand-name drugs relative to generic drugs and quickens the pace at which an enrollee reaches the OOP threshold (the point at which Medicare currently begins paying for 80 percent of

benefits through reinsurance). Under the current policy's treatment of the brand discount, enrollees who use more generics pay more OOP than those who use brand-name drugs. The second part of the recommendation excludes the manufacturers' discount from what counts toward an enrollee's OOP spending threshold. The change would equalize the treatment of brand-name drugs and generic drugs in the coverage gap. Because the recommendation affects only brand-name drugs, it would have less effect on enrollees with higher use of generic drugs and would not affect enrollees who use only generic drugs during the coverage-gap phase.

The recommendation's third part would provide more complete OOP protection to Part D enrollees by removing any cost sharing above the benefit's OOP threshold. Currently, high-cost enrollees who do not receive the LIS must pay 5 percent of the price of their prescriptions after they reach the threshold. Specialty medicines for certain conditions are priced at thousands of dollars per prescription, so 5 percent cost sharing can be a considerable expense on top of an OOP threshold that, in 2016, reaches \$4,850. The recommendation would remove cost sharing above Part D's OOP threshold.

IMPLICATIONS 6-1

Spending

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

Beneficiaries and providers

- Because this recommendation's first part would provide more of Medicare's 74.5 percent subsidy through capitated payments, plan sponsors would bear more insurance risk for their enrollees' benefit spending. To the extent that sponsors charged a larger risk premium to reflect greater insurance risk or purchased private reinsurance, the policy could increase plans' costs of doing business and put upward pressure on enrollee premiums. However, larger insurers, better positioned to shoulder more insurance risk independently and reinsure themselves, account for the vast majority of Part D enrollment. Plan sponsors with smaller numbers of enrollees could be more likely to purchase private reinsurance. Most parent organizations with smaller Part D enrollment
- are MA-PDs, some of which already purchase private reinsurance to cover unexpectedly high medical spending. Our discussions with private reinsurers suggest that those types of contracts could be modified to include drug benefits.
- The need for larger risk premiums or private reinsurance could be offset if more of Medicare's subsidy was provided through capitated payments; that is, plan sponsors would have greater motivation to better manage benefits of high-cost enrollees and negotiate larger discounts with pharmaceutical manufacturers and pharmacies. However, the net result of those two opposing forces (potentially higher costs of private reinsurance vs. greater motivation to manage benefits) is uncertain.
- This recommendation's second part would keep the current 50 percent manufacturers' discount on brand-name drugs that begins in the Part D benefit's coverage gap. However, because those discounts would no longer count as an enrollee's OOP spending, fewer non-LIS enrollees would reach Part D's OOP threshold. We estimate that in 2013, this situation would have applied to about 350,000 enrollees. However, to the extent that the policy change would encourage greater use of lower cost drugs, it could lead to lower OOP spending for those enrollees. The policy change would have less effect on enrollees with higher use of generic drugs and would not affect enrollees who use only generic drugs during the coverage gap phase. The recommendation would expose some beneficiaries to higher cost sharing in the coverage gap. We estimate that in 2013, all of the 700,000 non-LIS enrollees who reached the coverage gap would remain in the gap phase longer and would each pay, on average, about \$1,000 more in cost sharing.
- We estimate that the third part of this recommendation, when combined with the second part, would have eliminated cost sharing above Part D's OOP threshold for approximately 350,000 enrollees in 2013. On average, beneficiaries who reach the OOP threshold would have an average of \$1,000 less in cost sharing above the OOP threshold because of the new cap.

Greater financial incentives for enrollees with the low-income subsidy to use lower cost medicines

In 2015, Part D's LIS provided nearly 12 million low-income beneficiaries with help paying their premiums and cost sharing. Of these individuals, more than 7

million were dually eligible for Medicare and Medicaid. Another 4.6 million qualified for the LIS either because they received benefits through the Medicare Savings Programs or the Supplemental Security Income program or because they were eligible after they applied directly to the Social Security Administration. LIS enrollees are more likely than other Part D enrollees to be female; African American, Hispanic, or Asian American; and under age 65. They also tend to have poorer health status and higher risk scores. In 2015, about 70 percent of LIS enrollees were in PDPs, and 30 percent were enrolled in MA-PDs.

The maximum amounts of cost sharing that LIS enrollees pay out of pocket are set in law, and Part D plan sponsors cannot vary those amounts. In 2016, beneficiaries who are dually eligible for Medicare and Medicaid and other beneficiaries with incomes less than 100 percent of the federal poverty level (FPL) pay up to \$1.20 to fill a generic prescription, up to \$3.60 for brand-name drugs, and zero above Part D's OOP threshold. Other beneficiaries with incomes between 100 percent and 150 percent of the FPL (who meet certain asset tests) pay \$2.95 for generic prescriptions and \$7.40 for brand-name drugs.¹⁶ Most LIS enrollees do not face a coverage gap. However, a small number of individuals with a partial LIS must pay a \$74 deductible before paying reduced copayments and then 15 percent coinsurance in the coverage gap. Beneficiaries with the LIS who reside in long-term care institutions or who receive home and community-based services pay no cost sharing.

Differential cost sharing across formulary tiers is a fundamental tool used by plan sponsors to manage their enrollees' drug spending (Medicare Payment Advisory Commission 2016). This approach provides financial incentives to enrollees to use lower cost drugs. However, those financial incentives do not apply to LIS enrollees because the maximum OOP cost-sharing amounts for them are set by law. For example, if a full-benefit dual-eligible beneficiary filled a prescription through her PDP that used a benefit design that charged \$3 for a preferred generic drug and \$10 for other generics, the LIS enrollee would pay \$1.20, even if her prescription was not for a preferred generic. Part D's low-income cost-sharing subsidy would pay for the \$8.80 difference (\$10 minus \$1.20). Likewise, if the plan's benefit design charged \$35 for a preferred brand-name drug and \$85 for a nonpreferred brand, the LIS enrollee would pay \$3.60 out of pocket for a nonpreferred brand prescription and Medicare's low-income cost-sharing subsidy would pay \$81.40.

The amounts of cost sharing that Medicare pays on behalf of LIS enrollees are substantial. For example, in 2013, Medicare's low-income cost-sharing subsidy totaled \$19.5 billion—an amount much larger than the approximate \$5 billion Medicare paid for premiums on behalf of LIS enrollees. An analysis by Acumen LLC of the average percentage of cost sharing for LIS enrollees at different intervals of annual total spending helped us compare what LIS enrollees pay out of pocket with what Medicare pays on their behalf for cost sharing.

Table 6-8 (p. 186) shows cost-sharing amounts for LIS beneficiaries with annual total drug spending that occurred at different phases of the benefit.¹⁷ Cost-sharing amounts shown are for an enrollee with average annual spending in each spending range based on actual spending in 2013. For example, about 15 percent of LIS enrollees had total drug spending between \$1 and \$324 in 2013. Because many LIS enrollees were in plans with a deductible, the average cost sharing charged by plans for these enrollees was 85 percent of the total drug costs. However, most LIS enrollees paid nominal copayments out of pocket, and Medicare's low-income cost-sharing subsidy paid most of the deductible on their behalf. As a result, LIS enrollees with spending between \$1 and \$324 paid 13 percent of their drug costs, while Medicare's low-income cost-sharing subsidy paid 72 percent.

Twenty-one percent of LIS enrollees had drug spending between \$2,970 and \$6,954.51, which is the range of spending in which non-LIS enrollees face a coverage gap. However, LIS enrollees do not face a coverage gap; most continue to pay nominal copayments for each prescription, with Medicare paying the remaining cost-sharing amounts charged by their plans. Seventeen percent of LIS enrollees had spending high enough to reach Part D's OOP threshold (7 percent with spending between \$6,954.52 and \$9,999, plus 10 percent with spending of \$10,000 or more).

In its March 2012 report, the Commission recommended that the Congress give the Secretary authority to provide stronger financial incentives for LIS enrollees to use lower cost generics when available (Medicare Payment Advisory Commission 2012). At the time, a key rationale for the recommendation was that LIS enrollees made up the majority of beneficiaries who reached the catastrophic phase of the benefit. This rationale continues to be true; in 2013, LIS enrollees made up 75 percent of high-cost enrollees. Encouraging LIS enrollees to use lower cost generics could reduce the number of individuals who

**TABLE
6-8**

Cost-sharing amounts paid by LIS enrollees and by Medicare's low-income cost-sharing subsidy in 2013

Gross drug spending per beneficiary	Percent of LIS enrollees	Average spending per LIS enrollee*	Average percent paid in cost sharing			Average dollars paid in cost sharing		
			LIS enrollees' OOP cost sharing	LIS enrollees' OOP combined with LICs	LICs	LIS enrollees' OOP cost sharing	LIS enrollees' OOP combined with LICs	LICs
\$0	8%	\$0	N/A	N/A	N/A	N/A	N/A	N/A
\$1-\$324	15	146	13%	85%	72%	\$19	\$124	\$105
\$325-\$2,969	39	1,276	5	45	40	68	573	505
\$2,970-\$6,954.51	21	4,426	3	55	52	130	2,429	2,299
\$6,954.52-\$9,999	7	8,272	2	58	56	148	4,805	4,658
≥\$10,000	10	22,073	0.5	25	25	113	5,619	5,506

Note: LIS (low-income subsidy), OOP (out-of-pocket), LICs (low-income cost-sharing subsidy), N/A (not applicable). Beneficiary OOP includes all payments made by or for a beneficiary (excluding low-income cost sharing) that would be treated as OOP for the purpose of determining when he or she has reached the catastrophic phase of the benefit.

*Average across all LIS enrollees with total (gross) annual spending that falls within the spending ranges.

Source: MedPAC based on Acumen LLC analysis for MedPAC.

reach the catastrophic phase of the benefit and thereby reduce the amount Medicare pays to plans in individual reinsurance. It could also reduce Medicare's spending for low-income cost sharing.

The President's budget proposals for 2016 and 2017 included similar modifications to Part D's LIS copayment amounts. Specifically, the proposals would lower LIS copayments for generic drugs and double them for brand-name drugs. To protect beneficiaries, the Secretary would have authority to select only therapeutic classes with generic alternatives for which generic substitution would be clinically appropriate. She would also have authority to exclude brand-name drugs from this policy in therapeutic classes for which she determines that therapeutic substitution is not appropriate or for which no generics are available (Department of Health and Human Services 2016, Department of Health and Human Services 2015). Institutionalized LIS enrollees would continue to pay zero cost sharing, and LIS enrollees with a partial subsidy would pay the new copayment amounts above Part D's OOP threshold. For the President's 2017 budget proposal, the Congressional Budget Office estimated that this policy would reduce Medicare spending by \$7.2 billion over 5 years and by \$18.3 billion over 10 years (Congressional Budget Office 2016).

Some empirical research supports the idea that zero-dollar copayments could encourage greater use of generics and may improve medication adherence. One study based on 2008 Part D claims for statins that excluded LIS enrollees found that having a zero copayment for generic statins was associated with an especially large effect on generic use (Hoadley et al. 2012). More recently, CMS researchers examined the generic substitution rates of LIS enrollees and non-LIS enrollees in Part D plans that charged no copayment for generic drugs. (If an LIS enrollee's plan benefit design charges no copayment, the beneficiary pays nothing rather than the statutory amount.) The study found that in 2012, about 21 percent of plans had a generic tier with no copayment, and those plans enrolled about 11 percent of all Part D enrollees. Average rates of generic substitution were 1 percentage point to 3 percentage points higher for LIS enrollees and non-LIS enrollees (estimated separately) in plans that charged no generic copays (Centers for Medicare & Medicaid Services 2015b).

In discussions last year between plan sponsors and Commission staff, plan representatives were highly supportive of giving LIS enrollees stronger financial incentives to use lower cost options. Many of the individuals noted the lower use of generics by LIS enrollees, and some voiced frustration with plans' inability

to use differential cost sharing to a greater degree. Many plan sponsors noted that because of the statutorily set copayments, their plans that enroll higher shares of LIS enrollees use “leaner” formularies that cover fewer drugs, and they apply utilization management tools more frequently.

When Commission staff spoke with beneficiary advocates, they supported the idea of charging zero copayments for generics, but had strong concerns about any increases to LIS copayments for brand-name drugs. Given the limited incomes and poorer health status of the LIS population, beneficiary advocates believe the policy would be burdensome or that low-income beneficiaries would not fill prescriptions for needed medications (Leadership Council of Aging Organizations 2014). Advocates believe that a better approach would be for plans to contact prescribers directly about medically appropriate substitutions.

Since 2012, when the Commission last examined the issue of LIS cost sharing, the Food and Drug Administration (FDA) has approved the first biosimilar product, and other biosimilar products are under review.¹⁸ The current LIS copayment structure does not distinguish between biosimilars and their reference products; LIS enrollees would pay the same brand-name copayment in either case. The introduction of biosimilars may lead to lower prices over time, so Medicare may want to encourage their use when clinically appropriate to help keep the Part D program financially sustainable.

With that consideration in mind, a second recommendation would slightly modify the Commission’s recommendation on LIS cost sharing from 2012. The recommendation would have the Secretary consider moderately increasing financial incentives for LIS enrollees to use lower cost medicines, including generic drugs, preferred multisource drugs, and biosimilars. To protect beneficiaries, the Secretary would have authority to select therapeutic classes to which this policy would apply—classes that have generics or biosimilars available and for which substitution would be clinically appropriate. Plan sponsors would need to ensure that their prior authorization and their appeals and grievance processes allowed access to needed medications in cases where therapeutic substitution was not clinically appropriate.

RECOMMENDATION 6-2

The Commission’s second recommendation slightly modifies its 2012 recommendation on statutory copayment

amounts for Part D enrollees who receive the LIS. Specifically, the Commission recommends that:

The Congress should change Part D’s low-income subsidy to:

- **modify copayments for Medicare beneficiaries with incomes at or below 135 percent of poverty to encourage the use of generic drugs, preferred multisource drugs, or biosimilars when available in selected therapeutic classes;**
- **direct the Secretary to reduce or eliminate cost sharing for generic drugs, preferred multisource drugs, and biosimilars; and**
- **direct the Secretary to determine appropriate therapeutic classifications for the purposes of implementing this policy and review the therapeutic classes at least every three years.**

RATIONALE 6-2

Plan sponsors routinely use differential cost sharing to make generics and 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 than those faced by non-LIS enrollees. This recommendation would give the Secretary flexibility to determine clinically appropriate therapeutic classes and cost-sharing amounts, which would strengthen financial incentives to use lower cost drugs and biosimilars while ensuring affordability of medicines for LIS enrollees. By directing the Secretary to review the therapeutic classes at least every three years, the recommendation would ensure that the latest clinical evidence could be used to determine the appropriate therapeutic classes for applying this policy.

IMPLICATIONS 6-2

Spending

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

Beneficiaries and providers

- Lower copayments for generics, preferred multisource drugs, and biosimilars would reduce OOP costs for beneficiaries on generic, preferred

multisource, or biosimilar medications and for beneficiaries who switched from brand-name drugs and reference biologics. This change could increase beneficiaries' access to medications and improve adherence to therapies. Some plan sponsors could experience a decrease in the costs of providing the benefit if their LIS enrollees switched from brand-name drugs and reference biologics to generic and other preferred multisource drugs and biosimilars. Those lower costs would tend to decrease premiums for all enrollees and reduce subsidy payments from Medicare to Part D plans.

Increased flexibility to use formulary tools

If Part D plans were required to take on more risk, they would have stronger incentives to manage enrollees' drug spending. However, plan sponsors also need stronger tools to carry out that management, particularly in how they operate their drug formularies.

Formulary design is the key tool used by plans to manage drug benefits. Plan sponsors must decide which drugs to include on the formulary, which cost-sharing tier is appropriate for each drug, and whether a drug will be subject to prior authorization or other forms of utilization management. Those decisions, in turn, require that plan sponsors strike a balance between providing access to medications while encouraging enrollees to use lower cost therapies. Decisions about formulary design also affect plan sponsors' bargaining leverage with pharmacies and pharmaceutical manufacturers over drug prices and rebates.

Part D regulations and policy guidance were designed to ensure that Medicare beneficiaries, with their higher disease burden, have access to medications. The regulations limit how Part D plan sponsors operate their formularies compared with how the same sponsors manage formularies for their commercial populations. We first provide an overview of Part D formulary requirements and coverage determinations and then describe specific areas for recommended change.

Part D formulary requirements and coverage determinations

Law and regulations lay out specific requirements for Part D plan formularies. Plans must have a pharmacy and therapeutics (P&T) committee composed of members who meet certain requirements regarding background (physicians and pharmacists) and conflicts of interest.

P&T committees develop and review their formulary's structure, exceptions policies, and protocols for prior authorization and other forms of utilization management. In addition to considering drug prices, rebates, and cost effectiveness, P&T committees base decisions about plan coverage and formulary design on the strength of scientific evidence and standards of practice.

Part D plans must provide an adequate formulary. In that regard, CMS must review and approve each plan's formulary to ensure that it would not substantially discourage enrollment by any group of eligible individuals such as those with certain conditions. Under a "safe harbor" provision in regulation, many plan sponsors choose to avoid a rigorous review of their drug categories and classes by adopting model guidelines for therapeutic classes established by the U.S. Pharmacopeia.¹⁹ Plans must include coverage of the types of drugs most commonly needed by Part D enrollees as recognized in national treatment guidelines. For most drug classes, plans must cover at least two distinct drugs that are not therapeutically equivalent or bioequivalent. In addition, CMS requires that "all or substantially all drugs" in six protected classes be included in Part D plan formularies—anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. Because of these provisions, some analysts have noted that Medicare "limits the freedom of Part D plans to control their formularies" (Outterson and Kesselheim 2009).

As with commercial plans, Part D plans must allow formulary exceptions—coverage of a nonformulary drug under certain circumstances such as a patient's potential for an adverse reaction to the formulary drug or prior experience that the drug was ineffective for the patient. However, unlike commercial plans, Part D plans must also allow tiering exceptions—requests for the enrollee to pay lower preferred cost-sharing amounts for nonpreferred drugs. (Tiering exceptions do not apply to specialty tiers or to LIS copays, which are specified by law rather than part of a plan's benefit design and formulary structure.)

Medicare requires plan sponsors to establish coverage determination and appeals processes with the explicit goal of ensuring that plan formularies do not impede access to needed medications. The burden associated with navigating these processes varies from plan to plan. Part D law also requires sponsors to have a transition process to ensure that new enrollees, as well as current members

whose drugs are no longer covered or are subject to new restrictions, have access to the medicines they have already been taking.²⁰ The transition-fill policy is intended to give enrollees time either to find an alternative that is on the plan’s formulary or to initiate an exception request.

If an enrollee’s prescription claim is rejected at the point of sale, the pharmacy is required to provide the enrollee with written information about how to obtain a detailed written notice from the enrollee’s plan about why the benefit was denied and their right to an appeal. However, the enrollee must contact the plan to find the reason for the refusal and must initiate a request for a coverage determination with supporting justification from the prescriber.

Part D requires quicker adjudication time frames than for Medicare Advantage medical benefits because “the majority of Part D coverage requests involve prescription drugs an enrollee has not yet received, which increases the risk of adverse clinical outcomes if access to the drug is delayed” (Centers for Medicare & Medicaid Services 2016a). Plan sponsors must make a decision about exceptions and coverage determination within 72 hours of a request or within 24 hours for expedited requests. If the plan contacts the prescriber but is not able to obtain the supporting information needed to make a coverage determination within the allotted time, the plan must issue a denial and then process any subsequent information it receives as a redetermination.

In our discussions, stakeholders—beneficiary advocates, prescribers, plan sponsors, and CMS—have all noted frustrations with Part D coverage determinations, exceptions, and appeals (see text box about these processes, p. 190). A more efficient approach would be to resolve such issues at the point of prescribing through e-prescribing and electronic prior authorization rather than at the pharmacy counter. Such tools could reduce the need for coverage determinations and appeals and could increase the likelihood that beneficiaries receive an appropriate medicine at the pharmacy. Automated processes could also lower administrative burden and lead to a more uniform approach for beneficiaries, prescribers, and plans (American Medical Association 2015). Part D plan sponsors are required to support electronic prescribing, but e-prescribing is optional for physicians and pharmacies.²¹ While beneficiary advocates are generally supportive of such steps, some contend that they would not be sufficient to address persistent challenges (Medicare Rights Center 2016).

Revisit the protected classes

The “protected class” policy was intended to ensure access to medications in classes for which access cannot be adequately ensured through existing beneficiary protections. Plan sponsors are permitted to place protected-class drugs on preferred and nonpreferred cost-sharing tiers, but they cannot remove a drug altogether from their formulary, which limits their leverage in price negotiations. Because the policy requires open coverage of drugs in those classes, CMS noted in a 2014 proposed rule that the policy “presents both patient welfare concerns and financial disadvantages for the Part D program as a result of increased drug prices and overutilization.” The agency also noted that protected status may “substantially limit Part D sponsors’ ability to negotiate price concessions in exchange for formulary placement of drugs in these categories or classes” (Centers for Medicare & Medicaid Services 2014).

Part D restricts how plan sponsors may apply utilization management tools such as prior authorization for drugs in the protected classes. In the case of an enrollee just starting to take a protected-class drug, Part D guidance permits sponsors to apply utilization management tools. However, for enrollees who are already using a protected-class medication, plan sponsors may not use prior authorization or step therapy to steer the enrollee toward preferred alternatives.

In its 2014 proposed rule, CMS suggested applying a two-step test to determine which drug classes are of sufficient clinical concern to merit protection. The criteria included the following:

- hospitalization, persistent or significant disability or incapacity, or death likely will result if initial administration of a drug in the category or class does not occur within seven days of the date the prescription was presented to the pharmacy to be filled; and
- more specific CMS formulary requirements will not suffice to meet the universe of clinical drug-specific and disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

In other words, a drug class would not be given protected status unless a delay in obtaining a medication would likely result in serious health consequences and the clinical

Part D's exceptions and appeals process

The Part D appeals process is complex, involving multiple levels. After examining Part D's exceptions and appeals process, we found insufficient data to evaluate how well the process is working for beneficiaries to gain access to needed medications (Medicare Payment Advisory Commission 2015b, Medicare Payment Advisory Commission 2014c). We also found that the process can be time consuming and frustrating and may be burdensome for some individuals (Hargrave et al. 2015, Hargrave et al. 2012). Similarly, CMS audits continue to find that plans have difficulties in the areas of Part D coverage determinations, appeals, and grievances (Centers for Medicare & Medicaid Services 2015c). These findings suggest a need for increased transparency and streamlining of the coverage determination process so that beneficiaries and prescribers are not discouraged from seeking exceptions for needed medications.

At the same time, exceptions and appeals that routinely overturn plans' coverage decisions could undermine plans' efforts to manage drug spending. A representative of one plan sponsor we spoke with described the sponsor's experience in which the plan's negative coverage decisions of nonformulary drugs were routinely overturned (reversed) by an independent review entity (IRE). The plan sponsor was generally not successful in appealing IRE decisions, which were typically denied on the grounds that supporting statements provided by prescribers proved the medical necessity for the drug—even when those statements were extremely general such as, “this is the right drug for the patient.” Because a Part D plan's star rating includes how often its coverage decisions are overturned by the IRE, such cases can have a

chilling effect on a plan's willingness to use formulary tools—including on-formulary or off-formulary status to manage the use of expensive medications. That situation, in turn, can affect the rebate negotiations with pharmaceutical manufacturers.

CMS has expressed repeated concerns that some Part D sponsors reject claims inappropriately and are not fully compliant with transition-fill requirements (Centers for Medicare & Medicaid Services 2015c, Centers for Medicare & Medicaid Services 2012, Centers for Medicare & Medicaid Services 2010b). Recently, CMS applied civil and monetary sanctions against several Part D plan sponsors for failure to comply with regulations in areas such as formulary requirements, coverage determinations, and exceptions and appeals processes (Centers for Medicare & Medicaid Services 2016c).

In 2015, CMS conducted a “point-of-sale pilot” with four Part D plan sponsors to identify alternatives to beneficiaries having to request coverage determinations from their plans. Each sponsor took a somewhat different approach in identifying which drugs to focus on and how to communicate with prescribers and pharmacies. The pilot had mixed results in terms of helping beneficiaries to obtain an appropriate medication from the pharmacy. Plans that participated in the pilot found the process to be labor intensive, and the key difficulty appeared to be engaging prescribers (Centers for Medicare & Medicaid Services 2016d). Several participants suggested that more fruitful approaches would include promotion of e-prescribing, better real-time queries about formulary coverage at the point of prescribing, and broader use of electronic prior authorization. ■

needs of patients treated with one or more medications in that drug class cannot be met unless all Part D drugs in that class were included on a plan formulary. After reviewing medications in the six protected classes, in 2014, CMS proposed removing antidepressants and immunosuppressants for transplant rejection from protected status.²² (CMS also found that antipsychotics did not meet the two-part test. However, the agency did

not propose removing antipsychotics from protected-class status because of the clinical risk associated with untreated psychotic illness.) The Commission noted in comments to CMS that it was generally supportive of applying objective criteria in determining classes of clinical concern while balancing the goals of beneficiary access and welfare with Part D plans' tools to manage the drug benefit and appropriately constrain costs (Medicare Payment Advisory

Commission 2014a). Ultimately, however, CMS never adopted its proposed changes to the protected classes because of stakeholder concerns.

The Commission continues to support CMS's proposal to remove antidepressants and immunosuppressants for transplant rejection from protected status. The two classes have a number of generic versions of drugs available. In the case of antidepressants, a patient may need to use several drugs before finding effective treatment. Among commercial plans that are not subject to CMS's formulary requirements, our cursory review of several commercial formularies suggests that plans already include a number of generic drugs, each with different molecular structures, as therapeutic alternatives.

In the Commission's March 2016 report to the Congress, we noted that, when measured by individual national drug codes, prices for protected-class drugs showed a trend between 2006 and 2013 similar to that for all Part D drugs, rising by a cumulative 38 percent. However, when protected-class drugs were grouped to take generic substitution into account, their prices declined by a cumulative 16 percent over the same period (Medicare Payment Advisory Commission 2016). For this reason, the degree to which plans could achieve additional savings is unclear. To the extent that enrollees still use brand-name drugs in the antidepressant and immunosuppressant classes, the recommendation could give plan sponsors additional bargaining leverage with manufacturers.²³

Formulary changes

Continuity of a plan's formulary is very important for beneficiaries, allowing them to maintain access to the medications that were offered by their plan at the time they enrolled. However, there may be circumstances in which new clinical information about a drug or the entrance of a new competing therapy may warrant changes to a formulary in the middle of a benefit year. CMS's rules regarding formulary changes warrant examination.

CMS reviews two sets of formularies for each plan: (1) one set for the upcoming year and (2) proposed formulary changes that would be effective during the current (ongoing) benefit year (referred to as "midyear changes"). In both situations, plan representatives discussed streamlining CMS's process for reviewing applications.

In setting the formulary for the upcoming year, plan sponsors have limited time to ask CMS to change their

formularies in response to changing market conditions or new clinical information. To address this problem, CMS could consider offering one or more additional update opportunities. Plan sponsors submit their proposed formularies to CMS for the upcoming year no later than June as part of their bids.²⁴ CMS allows plans to submit limited types of proposed changes typically in July, but sponsors have no other opportunity to request changes until January of the new benefit year, for an effective date of March 1. Such a long gap can lead to difficulties in formulary administration, such as delays in adding drugs approved by the FDA late in the year or updating utilization management criteria in response to new FDA-approved indications.

There are also opportunities to streamline the process for midyear formulary changes, especially of the type that Part D guidance says CMS would generally approve. Part D regulations classify midyear formulary changes as either "enhancements" or "negative" changes. Adding a drug to the formulary or removing utilization management is an enhancement, while removing a drug from a formulary or setting new utilization management requirements is a negative change. Plan sponsors can implement enhancements to formularies at any time and are not required to seek CMS approval. However, plan sponsors must request and receive CMS approval before carrying out most negative changes (Government Accountability Office 2011). Plans must also give affected enrollees 60 days' notice before the change.

Part D guidance notes that the vast majority of negative changes to formularies are "maintenance changes" that CMS would generally approve. Examples of maintenance changes include (1) the plan sponsor's desire to remove a brand-name drug and substitute a new generic drug after the generic's entry in the market or after the publication of new clinical guidelines and (2) the plan's P&T committee recommendation to put a drug on a higher tier or to apply prior authorization. For maintenance changes, plan sponsors can send enrollees notification as soon as they submit their request to CMS. Part D guidance states that, if the plan has not heard from CMS within 30 days, it can assume that the change was approved. However, some plan sponsors wait for approval to avoid the risk of sending notifications on a change that CMS disapproves.

"Nonmaintenance changes" occur when a sponsor removes a drug from its formulary, moves a drug to a nonpreferred tier, or adds utilization management edits. Part D guidance states that plan sponsors must obtain

approval from CMS before carrying out nonmaintenance changes, and CMS officials have noted that it would tend to approve such situations only under extraordinary circumstances. When CMS approves such a change, enrollees currently taking the affected drug must be exempt from the formulary change for the remainder of the benefit year. Plan representatives told Commission staff that they recognize the need for CMS to evaluate nonmaintenance formulary changes. However, in their experience, CMS's criteria for approval or denial can be unclear, and some plan sponsors believe they have not had an opportunity to share information with CMS about why their P&T committee chose to propose such a change. In the case of nonmaintenance changes, sponsors may not send enrollees notice of the change until they have received formal approval from CMS. Plan sponsors report that the process of seeking approval for and implementing a maintenance change can sometimes take three to six months, and for this reason, some sponsors believe there is no value in submitting requests in the last one or two quarters of the benefit year.²⁵

Ideally, Medicare's review process would continue to guard against negative changes that affect beneficiaries' access to needed medications but would expedite midyear changes that CMS would generally approve. CMS could provide plan sponsors with greater flexibility to make certain maintenance changes, such as adding a generic drug and removing the brand-name version, without first receiving agency approval. Under that approach, the plan would still be required to file the change with CMS, and the plan sponsor would be subject to enforcement actions if it had not provided plan enrollees with timely access to the medication.

Rationalizing the exceptions process

Plan sponsors use utilization management tools such as quantity limits, step therapy, and prior authorization for expensive drugs to encourage use of lower cost therapies or to ensure appropriate use of an otherwise high-risk medication or medications that have a high likelihood of abuse. Plans also use prior authorization to help verify that a drug is being used for a covered Part D indication.

When an enrollee applies for a formulary exception, Part D guidance requires that the application be accompanied by a written or oral supporting justification from the prescriber that the medication is medically necessary. If the plan denies coverage, the beneficiary can appeal the decision. However, some plans have indicated that, unlike in the commercial sector, in Part D, the expectations for

justifications requesting coverage exceptions are not rigorous, resulting in approval of almost all requests. This situation can render utilization management tools ineffective. It can also undermine sponsors' efforts to negotiate rebates with pharmaceutical manufacturers. Plan sponsors note that the ease of formulary exceptions is a particular challenge with respect to "high-risk medications" that could pose serious side effects or increase risk of falls for elderly patients.

Instead, CMS could require standardized supporting justifications that provide more clinical information when requesting exceptions. Under a standardized approach, the process that plans use to obtain prescriber input needs to be not only specific and accurate but also relatively simple for prescribers, to reduce administrative burden.

Standardizing the type of clinical information that prescribers must submit in supporting justifications could improve the exceptions process and could help ensure that beneficiaries receive clinically appropriate drug therapies. Setting clear expectations for supporting justifications could also make the process more predictable for prescribers, thereby reducing their administrative burden. For example, CMS could develop a checklist of information needed related to the patient's requested medication, such as diagnosis, drug allergies, and rationale. Currently, when the pharmacy or plan contacts the prescriber but cannot receive a justification in a timely manner, the plan must issue a denial and the beneficiary must initiate the appeals process. However, a standardized approach could simplify the process of justifying a formulary exception for the prescriber, thereby reducing the delay associated with a beneficiary's efforts to file an appeal.

Ideas for managing the use of specialty products

Specialty drugs sometimes offer advances in patient care, and beneficiaries should be provided appropriate access to them. Because of their high prices, however, waste and inappropriate use of specialty drugs can have large consequences for spending. Greater use of tools to manage the use of specialty drugs could improve the quality of services for beneficiaries and provide plan sponsors with greater leverage in negotiations with drug manufacturers. Some approaches used by plans in the commercial sector include:

- using "split fills" (initial supplies that cover fewer days than is typical, e.g., 15 days rather than 30 days) to reduce waste, accompanied by a program to

improve the quality of patient care, such as monitoring for side effects and improving adherence.

- using two specialty tiers (preferred and nonpreferred), with more utilization management tools applied to products listed on the nonpreferred specialty tier. Such a tier structure, could, if used appropriately, reduce the need for nonformulary exceptions (because more expensive options could be placed on the nonpreferred tier rather than excluded from the formulary). This tier structure could also encourage competition among existing specialty drugs that are therapeutic substitutes. As more biosimilar products gain FDA approval, an additional specialty tier could also be effective at encouraging beneficiaries to consider substituting biosimilar products for reference products.

Another strategy most commercial health plans have adopted to manage the use of specialty drugs is to require that enrollees fill prescriptions through a limited network of specialty pharmacies. Specialty pharmacies often (but not always) deliver prescriptions by mail and offer additional support services to beneficiaries. Pharmacy benefit managers (PBMs) and health plans contend that specialty pharmacies can lead to better patient education and improved adherence. Specialty pharmacies can help prescribers navigate the clinical documentation needed to meet prior authorization requirements. The largest specialty pharmacies are owned by PBMs, and in some cases, they may be able to negotiate lower prices with drug manufacturers. However, a variety of business models fall under the term “specialty pharmacy,” and the interests served by some specialty pharmacies may not be aligned with those of payers or patients.

Unlike the commercial sector, Medicare guidance prohibits Part D plan sponsors from limiting where beneficiaries fill their prescriptions, so long as the pharmacy selected by the enrollee is in the plan’s network.²⁶ Many pharmacies would like to participate in the market for dispensing specialty drugs, especially in light of predictions about future growth in spending for those medications. The Commission intends to study specialty pharmacies further to identify ways to benefit from their management approach while ensuring appropriate access and healthy competition among pharmacies.

Other changes to the rules related to Part D’s formulary and benefit design would increase the ability of plan sponsors to manage drug use or bargain more effectively with pharmaceutical manufacturers. In general, providing

plan sponsors greater flexibility to manage drug use and spending has the potential to improve the financial outlook of the program. However, CMS will need to be vigilant to ensure that plan sponsors are using management tools to prevent inappropriate prescribing rather than to limit access to needed medications.

RECOMMENDATION 6-3

The Commission’s third recommendation relates to the use of formulary tools for managing Part D drug benefits. Current Medicare regulations and guidance limit plan sponsors from controlling their formularies to the degree they do for their commercial populations. This recommendation retains most conditions on Part D formularies such as requiring coverage of at least two drugs per therapeutic class, allowing enrollees to request coverage of nonformulary drugs, and allowing requests for an enrollee to pay the lower cost sharing of a preferred tier for a nonpreferred drug. However, the recommendation would allow for certain new flexibilities to meet changing market conditions while ensuring that beneficiaries maintain access to needed medications. Specifically, the Commission recommends that:

The Secretary should change Part D to:

- **remove antidepressants and immunosuppressants for transplant rejection from the classes of clinical concern,**
- **streamline the process for formulary changes,**
- **require prescribers to provide standardized supporting justifications with more clinical rigor when applying for exceptions, and**
- **permit plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications.**

RATIONALE 6-3

This third recommendation would provide plan sponsors with stronger formulary tools with which to manage their enrollees’ drug spending. It would complement the Commission’s 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 prescription drug spending more effectively.

The first part of this recommendation generally supports an approach CMS proposed in 2014 to apply objective criteria for determining which drug classes merit

protection. The intent behind the “protected classes” policy was to prevent sponsors from discouraging beneficiaries who are reliant on certain drugs from enrolling in certain plans and to mitigate the risk of interrupting therapy. However, because the policy requires plan sponsors to cover all drugs in the six classes, it limits the ability of plan sponsors to negotiate price concessions for those drugs. In 2014, CMS proposed objective criteria that evaluated the health consequences for beneficiaries of more limited access to medications. After applying those criteria to the six protected classes and noting the wide availability of generics in some of those classes, CMS proposed removing antidepressants and immunosuppressants for transplant rejection from protected status. CMS’s approach and its proposal to remove the two drug classes from protected status reached a balance between ensuring that beneficiaries have access to needed medications while giving plan sponsors greater room to negotiate price discounts.

Continuity of a plan’s formulary is very important for beneficiaries. However, there are circumstances in which negative changes (such as removing a drug from the formulary or adding a prior authorization requirement) are warranted. The second part of this recommendation would give plan sponsors one or more additional opportunities to modify their formulary before the start of an annual open enrollment period for a new benefit year. It also proposes to expedite midyear changes that CMS would generally approve. Plan sponsors would still be required to notify enrollees before making the change, but sponsors would no longer need prior CMS approval. CMS would verify the change after the fact, and plan sponsors would be subject to enforcement action if the change did not meet clear criteria for permissible changes.

Under the third part of this recommendation, CMS would require a standardized approach for prescribers to submit supporting justifications to plan sponsors to obtain a formulary exception for patients. Currently, requests for exceptions accompanied by a prescriber justification are typically approved, even if that statement is extremely general. By using a standardized approach, prescribers would have a more predictable process that could lead to less administrative burden. A standardized approach to providing clinical justifications for exceptions could also help ensure that beneficiaries receive clinically appropriate medicines.

The fourth part of this recommendation would direct CMS to develop guidance on using new tools for

specialty drugs. That guidance would have the intent of balancing beneficiaries’ access to needed medications with measures to limit the very expensive consequences of waste or inappropriate use of specialty products. For example, currently prescribers write prescriptions for a 30-day supply of medications, and the Part D plan must fill that prescription as written. However, many specialty medications such as oral oncology agents are changed or stopped early, and a portion goes unused. Under this part of the recommendation, CMS would develop guidance for plan sponsors to use an initial 15-day supply of a specialty drug to ensure that the patient has not abandoned treatment. CMS could also consider revising Part D guidance to allow for two specialty tiers, including a preferred one that offers lower cost sharing to encourage the use of lower cost biosimilars.

IMPLICATIONS 6-3

Spending

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

Beneficiaries and providers

- Several parts of this recommendation could affect beneficiaries who take certain antidepressants and immunosuppressants if their plan were to no longer cover their current drug. However, these classes contain a wide variety of therapy options, including many generics. Plans would continue to cover at least two drugs in those drug classes, and affected beneficiaries might find that they could switch medications. By including fewer drugs in those classes on their formulary, plan sponsors may be able to negotiate larger price discounts, which would lead to lower premiums and cost sharing for enrollees. If a patient’s clinical situation did not warrant switching drugs, the patient could apply for a formulary exception to obtain coverage of the original medicine. In this circumstance, the patient’s prescriber would need to submit a supporting statement with the clinical rationale for needing the original medicine.
- More extensive use of formulary changes when warranted would allow plan sponsors to respond more quickly to new clinical information and changing market conditions. In turn, this flexibility could give

sponsors more leverage in their price negotiations with manufacturers, potentially leading to lower enrollee premiums and cost sharing. Affected enrollees would continue to receive a 60-day written notice before the formulary change, including the rationale for the change, alternative treatments in the same therapeutic class, and instructions for pursuing a coverage determination. As with the protected classes policy change, midyear formulary changes would mean that some beneficiaries would need to switch medications or seek exceptions. Prescribers would need to submit a supporting statement if their patient had clinical reasons for continuing with their original therapy.

- Requiring that prescribers provide standardized justifications for a formulary exception could reduce unnecessary benefit costs and, in some cases, improve quality for the patient. To the extent that prescribers had to submit more rigorous clinical evidence in their supporting justifications than they do currently, that change could increase their workload. However, by instituting a standardized approach and allowing prescribers to submit the information in writing or orally, the relative amount of that burden would be lessened. ■

Endnotes

- 1 This amount includes reconciliation payments made during 2014 between Medicare and plan sponsors for benefits delivered in previous years. In 2014, incurred program spending totaled \$73.3 billion.
- 2 CMS assigns risk scores to enrollees based on demographic information and RxHCCs. Beginning in 2011, CMS replaced a single RxHCC model with five sets of model coefficients for long-term institutional enrollees, aged low-income enrollees, aged non-low-income enrollees, disabled low-income enrollees, and disabled non-low-income enrollees (Centers for Medicare & Medicaid Services 2010a). CMS uses regression analysis to determine dollar coefficients for each factor in the RxHCC model. CMS then creates relative factors for each demographic factor and condition category by dividing the coefficient by average predicted per capita spending so that the average risk score for all Part D enrollees is 1.0. CMS applies a normalization factor to risk scores used to predict spending in years after the calibration year to reflect changes in the population and in coding of diagnoses. CMS then calculates each enrollee's risk score by adding the relative risk factors applicable to the individual enrollee.
- 3 The industry does not have one consistent definition of specialty drugs, but these drugs tend to be characterized as high cost (e.g., Medicare defines specialty drugs based on the average price for a one-month supply; for 2016, the threshold is \$600 or more per month) and are used to treat a rare condition, require special handling, use a limited distribution network, or require ongoing clinical assessment. Most biologics are a subset of specialty drugs. See <http://www.ajmc.com/payer-perspectives/0213/The-Growing-Cost-of-Specialty-PharmacyIs-it-Sustainable>.
- 4 Starting in 2014, Part D contracts are subject to "medical loss ratio" requirements that require them to spend at least 85 percent of revenues on benefit costs and quality-improving activities. That policy also constrains plan profits.
- 5 This chapter uses the term *biologic* synonymously with *biological products* or *biologicals*, referring to drug products derived from living organisms. See Chapter 5 of the Commission's *Report to the Congress: Improving Incentives in the Medicare Program* (Medicare Payment Advisory Commission 2009a) for more detail.
- 6 The Commission examined this issue more closely in its June 2015 report within the context of prescription opioid use (Medicare Payment Advisory Commission 2015a).
- 7 The incurred amount of \$73 billion for 2014 differs from the \$78 billion described earlier because the larger amount includes reconciliation payments between Medicare and plan sponsors for benefits delivered in previous years.
- 8 These calculations for biologic products exclude insulin.
- 9 About 90 percent of long-term institutionalized Part D enrollees receive the LIS.
- 10 Private reinsurers and consulting actuaries that staff members interviewed for the Commissions' June 2015 report noted that they structure reinsurance contracts differently from Medicare's risk-sharing arrangements. They tend to use a higher dollar threshold than Part D's OOP limit before providing reinsurance coverage. For example, a private contract for specific stop loss might cover only the top 1 percent or 2 percent of enrollees as ranked by spending. By comparison, in 2013, about 8 percent of Part D enrollees reached the OOP limit. Interviewees said that the premium for such coverage would incorporate administrative costs and profits on the order of about 20 percent to 25 percent of covered benefits. However, such spending covered by private reinsurance would be considerably smaller than the amount of risk sharing Medicare provides currently (Medicare Payment Advisory Commission 2015a).
- 11 Because most LIS enrollees pay nominal copay amounts and face no coverage gap, they are not eligible for the brand-name discount and their OOP spending does not reach as high as the OOP threshold.
- 12 Examples of exceptions to this policy include cost sharing paid by individuals on behalf of the enrollee and payments by state pharmaceutical assistance programs. Medigap policies are prohibited from including drug coverage for Part D enrollees.
- 13 In 2020 and thereafter, enrollees will pay 25 percent cost sharing for both generics and brand-name drugs; to the enrollee, the manufacturer discount will no longer make the price of brand-name drugs appear relatively less expensive. However, because Part D plans must cover only 25 percent of the price of brand-name drugs but 75 percent of the price of generics, from a plan's perspective, the manufacturer discount will still lower relative prices for brand-name drugs.
- 14 However, the enrollee may apply to bona fide independent charity patient assistance programs (PAPs) for help with cost sharing. Pharmaceutical manufacturers can provide cash donations to independent charity PAPs without invoking anti-kickback concerns if the charity is structured properly. Guidance from the Department of Health and Human Services

- Office of Inspector General states that independent charity PAPs must provide assistance to broad rather than narrow disease groups, manufacturers must not exert direct or indirect control over the charity, and the PAP must not limit assistance to a subset of available products (Office of Inspector General 2014).
- 15 For this analysis, we assumed that each enrollee’s entire incremental spending in the coverage gap was for brand-name drugs. Among enrollees who reached the coverage gap, in 2013, on the order of 80 percent of their spending was for brand-name drugs and 20 percent for generics. By assuming instead that all of their coverage-gap spending was used for brands, we provide an estimate of the maximum numbers of enrollees who would remain in the coverage gap rather than reach the OOP threshold. We also tend to overstate the average increase in manufacturer discount under the policy change.
 - 16 For 2016, an individual is eligible to receive the low-income subsidy if his or her annual income is below \$17,820 (or \$24,030 for a married couple) and if the assets are below \$13,640 (or \$27,250 for a married couple).
 - 17 We took the share of drug costs that were paid by beneficiaries (OOP share) by annual spending levels in \$100 increments estimated by Acumen LLC and multiplied those amounts by the average spending by benefit phase, calculated using 2013 data on drug spending.
 - 18 A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products (<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/>).
 - 19 U.S. Pharmacopeia is a scientific nonprofit organization with the primary mission of setting standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements.
 - 20 The transition fill is a temporary one-time supply of up to 30 days of medication provided during the first 90 days in a plan for new enrollees and during the first 90 days of the new contract year for the existing enrollees. For individuals living in long-term care facilities, the temporary supply may be for up to 31 days and may be renewed as necessary during the entire length of the 90-day transition period.
 - 21 The exception is New York, which mandates electronic prescribing.
 - 22 CMS’s review panel found that antidepressants did not meet the first criterion: a seven-day delay in start of therapy would not put a patient at risk of hospitalization, incapacity, or death. For immunosuppressants, the panel found that while they met the first criteria, they did not meet the second one. CMS noted that “because widely accepted treatment guidelines recommend subclasses of drugs rather than specific, individual drugs, the panel did not believe that every drug product should be required for inclusion on Part D sponsors’ formularies” (Centers for Medicare & Medicaid Services 2013).
 - 23 While the share of prescriptions accounted for by generic drugs in classes with generic alternatives can be high, often exceeding 80 percent, the share of spending accounted for by brand-name drugs still may account for a large share of spending. For example, in 2013, 80 percent of the prescriptions for antidepressants were for generics, but spending for brand antidepressants accounted for 60 percent of total spending for that class.
 - 24 Sponsors submit formulary information to CMS on a formulary reference file (FRF)—a list of drugs that may be included on Part D plan formularies. CMS developed the FRF to have a normalized approach for reviewing and comparing plan formularies and to ensure that the same information can be uploaded to Medicare’s Plan Finder website. To maintain up-to-date FRFs, CMS coordinates with the Food and Drug Administration (which provides supporting files about which drugs have marketing approval), the National Library of Medicine (which provides normalized names and unique identifiers for drugs), and other contractors (for example, to update the Plan Finder with biweekly price information).
 - 25 CMS estimates that in 2015, the agency took an average of 15 days to review and respond to maintenance changes and approximately 37 days to review and respond to nonmaintenance changes. In addition to CMS’s review time, plan sponsors also include time required for new additions to the formulary reference file (described in endnote 24) as well as for notification of affected beneficiaries.
 - 26 CMS regulation states that Part D plans may not restrict access to certain Part D drugs to “specialty” pharmacies within their Part D network in such a manner that contravenes the convenient access protections of Section 1860D–4(b)(1)(C) of the Social Security Act and 42 CFR Section 423.120(a). An exception is if a *manufacturer* of a specialty medication has limited the distribution of its product to certain authorized pharmacies. In this situation, the Part D enrollee would be able to fill that prescription only at one of the designated (specialty) pharmacies.

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