CHAPTER 14

Status report on Part D

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Chapter summary

Each year the Commission provides a status report on Part D to:

- provide information on beneficiaries' access to prescription drugs—including enrollment figures and benefit and design changes—program costs, and the quality of Part D services; and
- analyze changes in plan bids, premiums, benefit designs, and formularies.

In 2012, Medicare spent $62.5 billion for the Part D program, accounting for over 10 percent of total Medicare spending. In 2013, over 35 million Medicare beneficiaries were enrolled in Part D, with about 64 percent of Part D enrollees in stand-alone prescription drug plans (PDPs) and the rest in Medicare Advantage–Prescription Drug plans (MA–PDs). Monthly premiums averaged about $30 across all plans. The actual premium paid by individual beneficiaries depends on their selected plan and income level, as well as whether they are subject to Part D's late enrollment penalty. In 2014, a total of 1,169 PDPs are offered nationwide along with 1,615 MA–PDs. MA–PD enrollees are much more likely than those in PDPs to receive basic and supplemental benefits combined in their drug plan. Most enrollees report high satisfaction with the Part D program.

An increasing number of plans are adding a nonpreferred generic tier, in some cases with a substantially higher cost-sharing amount relative to the preferred

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generic tier. In addition, we are seeing a trend toward the use of tiered network pharmacies that further stratifies cost sharing so that the amounts are lower if a beneficiary fills medications at a pharmacy that is designated as preferred. Both of these strategies provide financial incentives for enrollees to use a lower cost drug (or setting), potentially reducing program costs. However, the use of such financial incentives, while potentially lowering the cost of providing the basic benefit, could increase Medicare's spending for the low-income subsidy (LIS).

Although we continue to see a large number of plans in Part D, it is not clear whether the competition among plans is providing strong incentives for cost control, particularly once a beneficiary enters the catastrophic phase of the benefit, in which Medicare pays for 80 percent of the costs in reinsurance. The Commission will continue to explore how the program could be restructured to provide stronger incentives for plans to control drug spending.

Access to prescription drug coverage—In 2013, about 68 percent of Medicare beneficiaries were enrolled in Part D plans. An additional 6 percent received their drug coverage through employer-sponsored plans that receive Medicare's retiree drug subsidy. In 2011, the most recent year for which data are available, 12 percent had no drug coverage or coverage less generous than Part D. Our previous analysis showed that beneficiaries with no creditable coverage tended to be healthier on average. More than half reported not joining Part D because they did not take enough medications to need such coverage. Among Part D plan enrollees, 11.2 million individuals (about 32 percent) received the LIS. Although surveys suggest high satisfaction with Part D among the enrollees, about 6 percent reported having trouble obtaining needed medications. Access to medications depends on multiple factors. We examined available data on Part D's exceptions and appeals process but found insufficient data to evaluate the effectiveness of the process. We also found that the process is complex and burdensome for many individuals. Our review suggests a need for additional data on the outcomes of the exceptions and appeals process and a need for a more transparent and streamlined process.

Benefit offerings for 2014—The number of plan offerings remained stable between 2013 and 2014, with a modest increase in PDP offerings and slightly fewer MA–PDs (1,615 compared with 1,627 in 2013). Beneficiaries will continue to have between 28 and 39 PDPs to choose from in their region, depending on where they live, along with many MA–PDs. MA–PDs continue to be more likely than PDPs to offer enhanced benefits that include some coverage of the gap—the period between when Part D's initial coverage ends and when the enrollee meets the out-of-pocket threshold to enter the catastrophic phase of the benefit. For 2014, more premium-

free PDPs will be available to enrollees who receive the LIS; 352 plans qualified compared with 331 in 2013. A growing number of plan sponsors are choosing to offer preferred pharmacies in their network, with potentially significant price differentials for beneficiaries. In 2014, over 70 percent of all PDPs have tiered pharmacy networks with lower cost sharing at preferred pharmacies.

Part D spending—Between 2007 and 2012, Part D spending increased from $46.7 billion to $62.5 billion (an average annual growth of about 6 percent). In 2012, LIS payments continued to be the single largest component of Part D spending, while Medicare's reinsurance payments continue to be the fastest growing component, growing at an average annual rate of 14 percent between 2007 and 2012. Aggregate Part D payments to plans continue to grow at a faster rate than the growth in Part D enrollment. The "excess" growth in payments appears to be driven in large part by the growth in the average price of drugs filled, particularly among enrollees receiving the LIS. As in the past, we find that drug utilization by Part D enrollees with high spending was driving faster growth in payments for LIS and reinsurance compared with payments for the basic benefits. In 2011, the changes made by the Patient Protection and Affordable Care Act of 2010 (PPACA) to phase out the coverage gap may have increased the number of enrollees with high spending. According to our analysis of the Part D claims data, only 6 percent of the non-LIS enrollees who reached the catastrophic phase of the benefit spent $4,550 out of pocket (OOP), the amount of the OOP limit for 2011. Others met the OOP limit with the combination of their OOP spending and the manufacturer discounts mandated in PPACA.

Change in Part D bids—The average costs for basic Part D benefits are expected to grow by 4 percent between 2013 and 2014, but plan sponsors are expecting significant changes in costs for individual components of the basic benefit: a decrease of over 10 percent for the direct subsidy and an increase of about 20 percent for the reinsurance component. ■

Each year since 2006, the Commission has provided a status report on Medicare's Part D program and made recommendations as necessary. To monitor the ability of the program—under its competitive approach—to meet Medicare goals of maintaining beneficiary access while holding down program spending, we examine several performance indicators: beneficiaries' access to prescription drugs (including data on enrollment and changes in Part D plan benefit designs and formularies for 2014), program costs, and quality of services.

Background

Medicare's payment system for Part D is different from its prospective payment and fee-for-service payment systems for Part A and Part B services. For Part D, Medicare uses competing private plans to deliver prescription drug benefits; instead of setting prices administratively, Medicare's payments to Part D plans are based on bids submitted by plan sponsors.

Benefit structure

Medicare defines a standard Part D benefit structure with parameters that change at the same rate as the annual change in beneficiaries' average drug expenses (Table 14-1). For 2014, the defined standard benefit includes a $310 deductible and 25 percent coinsurance until the enrollee reaches $2,850 in total covered drug spending (not shown in table). The reduction in 2014 in the deductible and other benefit parameters reflects a decrease in average drug expenses CMS estimated for the August 2012 through July 2013 period. Enrollees exceeding that spending total face a coverage gap up to an annual threshold of $4,550 in out-of-pocket (OOP) spending that excludes the cost sharing paid by most sources of supplemental coverage, such as employer-sponsored policies. Enrollees with drug spending exceeding that amount pay the greater of either $2.55 to $6.35 per prescription or 5 percent coinsurance.

Before 2011, enrollees exceeding the initial coverage limit were responsible for paying the full discounted price of covered drugs (usually without reflecting manufacturers' rebates) up to the annual OOP threshold. Because of changes made by the Patient Protection and Affordable Care Act of 2010 (PPACA), since 2011, beneficiaries face reduced cost sharing for both brand-name and generic drugs filled during the coverage gap.[1] In 2014, cost sharing for drugs filled during the gap phase is 47.5 percent for brand-name drugs and 72 percent for generic drugs.[2] An individual with no other source of drug coverage reaches the $4,550 limit at $6,690.77 in total drug expenses.[3]

Formularies

In Part D, each plan sponsor uses one or more formularies—lists of drugs the plan covers and the terms under which it covers them—to manage the cost and use of prescription drugs. When designing formularies, sponsors attempt to strike a balance between providing enrollees with access to medications and controlling growth in drug spending, which they accomplish by negotiating drug prices and dispensing fees with pharmacies and negotiating rebates with pharmaceutical manufacturers, as well as by managing enrollees' utilization. Part D sponsors rely on clinicians (typically,

TABLE 14–1 **Parameters of the defined standard benefit**

	2006	2013	2014
Deductible	$250.00	$325.00	$310.00
Initial coverage limit	2,250.00	2,970.00	2,850.00
Annual out-of-pocket spending threshold	3,600.00	4,750.00	4,550.00
Total covered drug spending at annual out-of-pocket threshold	5,100.00	6,954.52*	6,690.77*
Minimum cost sharing above annual out-of-pocket threshold:			
Copay for generic/preferred multisource drug prescription	2.00	2.65	2.55
Copay for other prescription drugs	5.00	6.60	6.35

Note: *Total covered drug spending at annual out-of-pocket threshold depends on the mix of brand and generic drugs filled during the coverage gap. The amounts for 2013 and 2014 are for an individual not receiving Part D's low-income subsidy who has no other supplemental coverage.

Source: CMS, Office of the Actuary.

physicians and pharmacists who serve on a pharmacy and therapeutics committee) when deciding which drugs to list, subject to CMS regulations and requirements. Sponsors also select the cost-sharing tier for each listed drug (if using a tiered formulary structure) and determine whether to apply any utilization management tools, such as prior authorization. Making all medications readily accessible at relatively low levels of cost sharing can lead to a monthly plan premium that is high relative to a sponsor's competitors, whereas an overly restrictive formulary may keep a plan's premium competitive but make the plan less attractive to enrollees because it covers a more limited number of drugs.

Premiums

In 2013, monthly beneficiary premiums averaged about $30 across all plans. The actual premium paid by individual beneficiaries depends on their selected plan. Two other factors affect the amount of premium paid by a given enrollee: the enrollee's income level and whether the enrollee is subject to Part D's late enrollment penalty (LEP).

As a result of PPACA changes, the premium subsidy for higher income beneficiaries is lower than the statutorily defined subsidy of 74.5 percent. Similar to the income-related premium for Part B, the reduced subsidy applies to individuals with an annual adjusted gross income greater than $85,000 and to couples with an adjusted gross income greater than $170,000. A beneficiary whose income exceeds these levels pays an income-related monthly adjustment amount in addition to the Part D premium paid to a plan. The adjustment amount ranges from $12.10 to $69.30 per month in 2014, depending on income. Nearly 1.5 million beneficiaries were subject to the reduced premium subsidy in 2013.[4]

Individuals enrolling in Part D outside of their initial enrollment period must have proof that they had drug coverage as generous as the standard benefit under Part D (i.e., creditable coverage) to avoid the LEP. The process for verifying a beneficiary's prior drug coverage status often requires individuals to submit a document to the plan showing that they had creditable coverage before joining the plan. This process contrasts with how the penalty works under Part B, in which the onus is on CMS to determine whether the late-enrolling beneficiary is subject to the penalty.

The number of LEP-related appeals submitted to an external review entity (MAXIMUS) between 2008 and 2012 ranged from nearly 34,000 cases to about 72,000 cases. According to data from MAXIMUS, the majority of the cases that are not dismissed or withdrawn are overturned, and thus the penalty is not applied.

The high reversal rate observed for the appeals related to the LEP suggests that plans' processes used to verify enrollees' prior creditable coverage status may not be effective. Further, the resolution of cases in which the penalty is incorrectly applied may be delayed by limited awareness among enrollees of the penalty. Anecdotal evidence suggests that many enrollees are confused by the higher premiums they are charged and do not realize that the higher charge is due to the penalty until their cases go through the appeals process, which may also not be well understood.[5]

Competitive design

Part D uses a competitive design to give plan sponsors incentives to offer beneficiaries attractive prescription drug coverage while controlling growth in drug spending. In contrast to the administrative prices Medicare uses to pay providers for Part A and Part B covered services, Medicare's payments to plans are based on bids submitted by plan sponsors. When designing Part D, policymakers envisioned that plans would compete for enrollees based on their premiums, formularies, quality of services, and network of pharmacies. The idea was that competition among plans that bear insurance risk would provide strong incentives for plan sponsors to manage drug use and keep spending in check. To encourage entry of plans into a market that had not existed before—the provision of stand-alone drug coverage—policymakers included risk-sharing features that would temper incentives for sponsors to engage in selection behavior and features that would pay plans more for higher cost enrollees (see text box, pp. 362–363).

Part D enrollees' access to prescription drug benefits

Implementation of the Part D program in 2006 increased the share of beneficiaries who have some drug coverage from 75 percent before Part D to about 90 percent.[6] In general, Part D has improved Medicare beneficiaries' access to prescription drugs. All individuals have access to Part D plan options. Some beneficiaries continue to receive drug coverage through former employers.

TABLE 14–2 **Nearly three-quarters of beneficiaries had drug coverage through Part D plans or employer plans receiving RDS, 2013**

	Beneficiaries	
	In millions	Percent of Medicare enrollment
Medicare enrollment	52.3	100%
Part D enrollment		
Part D plans	35.7	68.3*
Plans receiving RDS**	3.2	6.1
Total Part D	38.9	74.4

Note: RDS (retiree drug subsidy). Figures are based on annual enrollment numbers reported in the Medicare Board of Trustees' report. Totals do not match those reported in Table 14-3, which are based on enrollment as of March 1, 2013. The remaining 25.6 percent of beneficiaries (not enrolled in Part D) received drug coverage through other sources or had no drug coverage. Totals may not sum due to rounding.
*About 43 percent in stand-alone prescription drug plans and 25 percent in Medicare Advantage–Prescription Drug plans.
**Excludes federal government and military retirees covered by either the Federal Employees Health Benefit Program or the TRICARE for Life program.

Source: MedPAC based on Table IV.B8 and Table V.B4 of the 2013 annual report of the Boards of Trustees of the Medicare trust funds.

In 2013, nearly three-quarters of Medicare beneficiaries were in Part D plans or employer plans receiving Medicare's retiree drug subsidy

In 2013, about 68 percent of an estimated 52.3 million Medicare beneficiaries were enrolled in Part D plans. This share has grown since the program began in 2006, with Medicare Advantage (MA) plans accounting for more than half of the growth in Part D enrollment between 2006 and 2013. An additional 6 percent of Medicare beneficiaries received their drug coverage through employer-sponsored plans that received Medicare's retiree drug subsidy (RDS), a drop from about 15 percent observed during the first few years of the program (Table 14-2).[8] Employers no longer offering drug coverage to their retirees typically move their Medicare-eligible members to Part D, typically to employer group waiver plans.[9] Some beneficiaries receive their drug coverage through other sources of creditable coverage, including the Department of Veterans Affairs, TRICARE (the Department of Defense's health benefit for retired military members), and other payers.

About 12 percent of beneficiaries had no drug coverage or coverage less generous than Part D's standard benefit in 2011 (the most recent year for which data are available), which is somewhat higher than the 10 percent reported by CMS in previous years. Research indicates that beneficiaries who do not enroll in Part D tend to be healthier and have lower drug spending (Medicare Payment Advisory Commission 2013).

In 2013, about 11 million individuals, or 32 percent of Part D enrollees, received the low-income subsidy (LIS). Of those, nearly 7 million were dually eligible for Medicare and Medicaid. Another 4 million qualified for the LIS either because they received benefits through the Medicare Savings Programs or the Supplemental Security Income program or because the Social Security Administration determined that they were eligible after they applied directly to that agency. Among LIS enrollees, about three-quarters (8.3 million) were enrolled in stand-alone prescription drug plans (PDPs) and the rest (2.8 million) were in Medicare Advantage–Prescription Drug plans (MA–PDs) (Table 14-3). CMS randomly assigns most LIS enrollees to PDPs that qualify as premium-free plans, but enrollees may choose a different plan. As a result, a much smaller share of MA–PD enrollees receive the LIS (about 22 percent compared with nearly 37 percent for PDPs).

Part D enrollment varies across regions

Part D enrollment varies geographically. In 2012, enrollment ranged between 39 percent and 71 percent of Medicare beneficiaries across the 34 PDP regions, with the

TABLE 14–3 **Part D enrollment by plan type and LIS status, 2013**

		Plan type	
	All Part D	PDP	MA–PD
Beneficiaries (in millions)	35.3	22.5	12.8
By LIS status			
LIS	11.2	8.3	2.8
Non-LIS	24.2	14.2	10.0

Note: LIS (low-income subsidy), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Figures based on enrollment as of March 1, 2013. Totals do not match those in Table 14-2, which is based on annual enrollment reported in the Medicare Boards of Trustees' report. Totals may not sum due to rounding.

Source: MedPAC based on monthly Part D enrollment data as of March 1, 2013 (http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/LIS-Enrollment-by-Plan.html).

Changing priorities for sharing risk

Two of Part D's risk-sharing arrangements between Medicare and private drug-plan sponsors were devised with the primary goal of ensuring plan entry and formation of competitive markets across the country:

- risk corridors to encourage entry of private providers into a market that had not existed before—that is, the provision of stand-alone drug coverage; and
- individual reinsurance to limit the insurance risk faced by sponsors (which also tempers incentives for sponsors to engage in selection behavior) (see "Aggregate program costs" (p. 375) for more detail on risk corridors and individual reinsurance).

Today, we continue to see a sizable number of plans available in every region of the country, with between 12 percent and 15 percent of enrollees willing to switch plans to lower their premiums, cost sharing, or both (Hoadley et al. 2013b, Suzuki 2013). A larger share are likely comparing their plan options. We heard from some participants in Commission-sponsored focus groups that they regularly compare plan options, although researching plan options did not always lead them to switch plans (Hargrave et al. 2012). It is not clear, however, whether having a large number of plans has led to robust competition and strong incentives for cost control.

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 relatively slowly, while benefit spending on which sponsors bear no insurance risk (low-income cost sharing) or limited risk (the catastrophic portion of the benefit, in which Medicare provides 80 percent reinsurance) has grown much faster. This evidence suggests that sponsors have been less aggressive or successful at cost containment when they were at less risk for benefit spending. The phase-out of the coverage gap that began in 2011 will likely continue to increase the number of people reaching the catastrophic phase of the benefit, further driving the growth in spending for reinsurance.

In most years, Medicare has, on net, collected risk-corridor payments from plans. That is, on average, plans have been making profits above and beyond what is built into their bids. There are many factors that affect plan profits. For example, effective management of enrollees' drug use or higher than expected rebates from manufacturers could result in unexpected profits.

In recent years, more plans have incorporated preferred and nonpreferred tiers for both brand and generic drugs, with higher cost-sharing amounts for nonpreferred tiers compared with the preferred tiers (see "Notable Changes for 2014 in Benefit Offerings," p. 372). In addition, we are seeing a trend toward the use of tiered network pharmacies that further stratifies cost sharing so that the amounts are lower if a beneficiary fills medications at a pharmacy that is designated as preferred (see text box on trend toward use of tiered pharmacy networks, pp. 370–371). Both of these strategies provide financial incentives to enrollees to use a lower cost drug (or setting), potentially reducing program costs. However, the use of such financial incentives, while potentially lowering the cost of providing the benefit for some beneficiaries, could increase Medicare spending for low-income subsidy (LIS) enrollees. LIS enrollees' out of pocket (OOP) spending is limited to amounts set in statute.[7] Higher cost sharing for these beneficiaries—for drugs on nonpreferred tiers or charged at nonpreferred pharmacies—is paid for by Medicare through a low-income cost-sharing subsidy.

Another indicator of how well sponsors contain costs is whether they have been able to curb growth in prices for Part D drugs. Again, the evidence is mixed. Generally, sponsors have been successful at encouraging enrollees to use generic alternatives when available. However, they have been less successful with their LIS enrollees. Sponsors typically have large cost-sharing differentials between brand and generic drugs to encourage their enrollees to use generic medications (Hoadley et al. 2012). Those differentials do not apply to LIS enrollees because their OOP spending is limited to the statutorily set amounts. Finally, the prices for unique drugs and biologics have grown rapidly. Because those products lack clear substitutes, sponsors

(continued next page)

Changing priorities for sharing risk (cont.)

have little leverage for price negotiations. As more drugs are introduced with very high launch prices, the use of these expensive drugs and biologics is likely to accelerate the growth in spending for reinsurance.

Given this evidence, policymakers may want to reevaluate the relative priority of policy goals for Part D since there is a trade-off between risk sharing and cost control. In December 2010, we convened a half-day session with a panel of eight outside experts to evaluate Part D's mechanisms for sharing risk with plan sponsors (Schmidt 2011). Panelists generally agreed that Part D's 80 percent reinsurance takes away the urgency for sponsors to manage prescription use among enrollees who use the most drugs (high-cost enrollees). One panelist pointed out that the rebates sponsors receive from manufacturers for brand-name drugs dispensed to high-cost enrollees can more than offset the 15 percent of benefit spending that sponsors must pay. Panelists discussed several ways to restructure Part D's risk-sharing arrangement. For example, Part D could require plan sponsors to pay more than 15 percent of benefit spending above the catastrophic threshold. If policymakers change Part D's reinsurance mechanism, they may also need to give sponsors greater flexibility in using formularies to contain costs, particularly to manage the costs of expensive drugs with few or no substitutes.

As policymakers try to address the growing costs of Part D's reinsurance, they should also explore how plans can do a better job of managing costs for LIS enrollees. Over 80 percent of the enrollees who reach Part D's catastrophic phase of the benefit receive the LIS, with a significant portion of reinsurance payments made on behalf of LIS enrollees. In addition, the subsidy for LIS enrollees has grown to be the single largest component of Part D spending. These factors and the trends toward the use of tiered cost sharing suggest the need to make changes that would increase incentives to manage drug spending for LIS enrollees. In our March 2012 report, the Commission recommended that the Congress give the Secretary the authority to provide stronger financial incentives to use lower cost generics when they are available (Medicare Payment Advisory Commission 2012). Another option may be to factor in both the premium and the expected low-income cost-sharing amounts to determine which plans would be available to LIS enrollees at no premium.

There was also considerable consensus among panelists that Part D entails less risk than commercial insurance that covers both medical and prescription drug services, primarily because of the general predictability of an individual's drug use from one year to the next. Most panelists thought that removing the risk corridors would not substantially affect sponsors' decisions about whether to stay in the market. There was a weaker consensus about the effects of removing the risk corridors on sponsors' incentives to contain costs. When the law that enacted Part D was passed, the Congressional Budget Office expected that plan sponsors would not manage drug spending as aggressively in the presence of risk corridors as they might otherwise because they would be insulated from losses resulting from less-aggressive management. As mentioned, in most years, on net, Medicare has collected a portion of unanticipated profits, over and above the returns built into plan bids. If policymakers decide to remove risk corridors, other policy changes would be needed as well to ensure that sponsors bear more insurance risk and Medicare's payments do not result in plans making profits over and above those built into their bids year after year. ■

lowest in region 34 (Alaska) and the highest in region 32 (California) (see online Appendix 14-A, available at http://www.medpac.gov). Part D enrollment tends to be lower in states with large employers that receive Medicare's RDS—Michigan and Alaska, for example. Between 2011 and 2012, most regions experienced a reduction in the share of beneficiaries receiving drug coverage through former employers, with a corresponding increase in the share of beneficiaries enrolled in Part D plans. The reductions were generally small, ranging from 1 percent to 3 percent, with the exception of region 4 (New Jersey), region 13 (Michigan), and region 21 (Louisiana), where the reductions were between 5 percent and 9 percent. In region 5 (Delaware–District of Columbia–Maryland), region 7 (Virginia), and region 34 (Alaska), the share of beneficiaries in Part D plans or in employer plans

TABLE 14–4 **MA–PD enrollees more likely to be in enhanced plans with no deductible, 2013**

	PDP		MA–PD	
	Number (in millions)	Percent	Number (in millions)	Percent
Total	18.0	100%	8.5	100%
Type of benefit				
Defined standard	0.5	3	0.1	1
Actuarially equivalent*	10.5	58	0.7	7
Enhanced	7.1	39	8.6	92
Type of deductible				
Zero	8.1	45	8.2	89
Reduced	0.6	3	0.8	9
Defined standard**	9.4	52	0.2	2

Note: MA–PD (Medicare Advantage–Prescription Drug [plan]), PDP (prescription drug plan). The MA–PD enrollment described here excludes employer-only plans, plans offered in U.S. territories, 1876 cost plans, special needs plans, demonstrations, and Part B–only plans. Totals may not sum due to rounding.
*Includes actuarially equivalent standard and basic alternative benefits.
**$325 in 2013.

Source: MedPAC analysis of CMS landscape, plan report, and enrollment data.

receiving the RDS were lower than in other regions. This finding may be because a higher proportion of beneficiaries receive drug coverage from other sources such as the Federal Employee Health Benefits Program or the Indian Health Service.

Most beneficiaries have access to both stand-alone PDPs and MA–PDs. In general, MA–PD enrollment is high in regions with higher MA penetration. For example, in 2012, more than 45 percent of Part D enrollees were in MA–PDs in parts of the West (Arizona, California, Colorado, Idaho, Nevada, and Utah) and in Florida, Hawaii, and New York. By comparison, in other parts of the Northeast, Midwest, and central states, fewer than 20 percent of Part D enrollees were in MA–PDs.

The number of beneficiaries receiving Part D's LIS also varies considerably by region. In 2012, the share of these beneficiaries ranged from 26 percent in the upper Midwest and several central western states to 60 percent in Alaska. The number of beneficiaries who receive Part D's LIS is related to many factors, such as underlying rates of poverty in each region, the degree to which a state's Medicaid program reaches out to enroll eligible individuals, and the criteria states use to determine eligibility for their Medicaid programs.

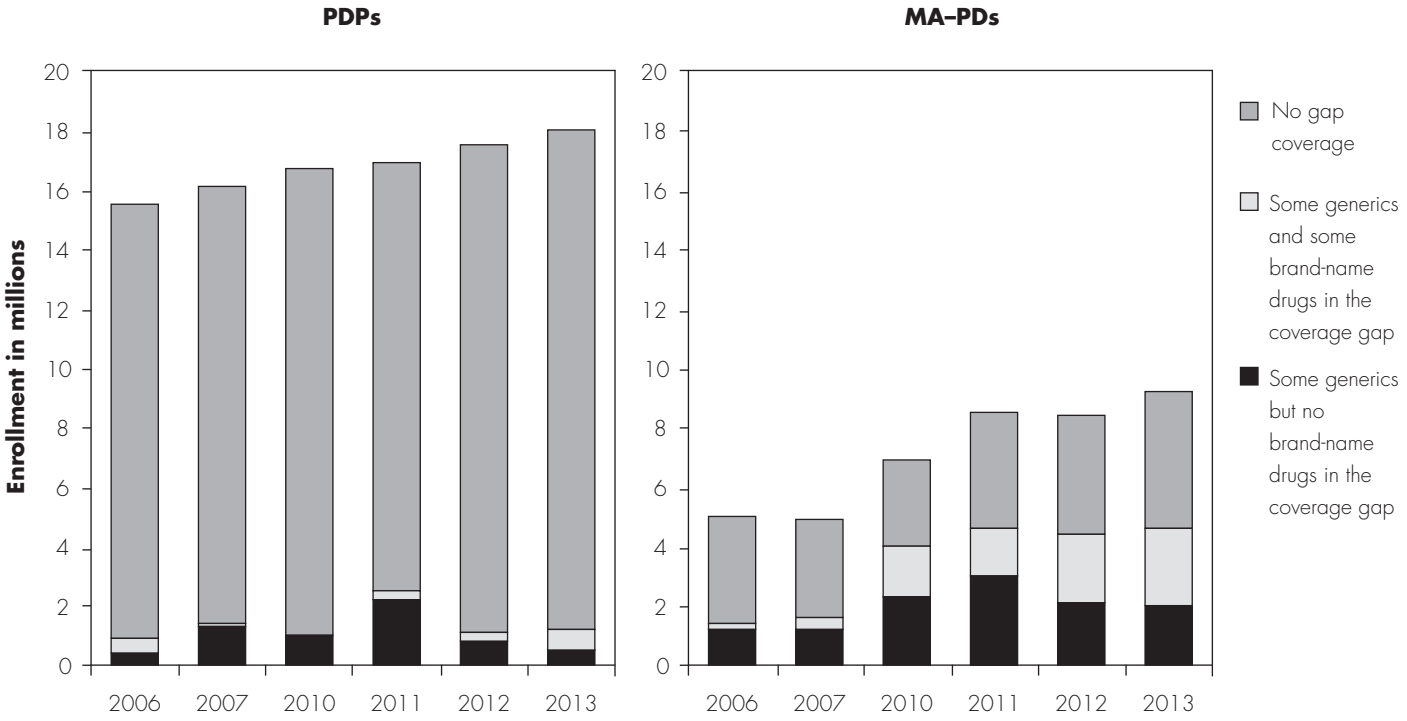
Most enrollees are in plans that differ from the defined standard benefit

Access to prescription drugs can be affected by the type of plan one chooses. Most Part D enrollees are in plans that differ from Part D's defined standard benefit; these plans are actuarially equivalent to the standard benefit or are enhanced in some way. Actuarially equivalent plans have the same average benefit value as defined standard plans but a different benefit structure.[10] For example, a plan may use tiered copayments (e.g., charging $5 per generic drug and $50 for a brand-name drug) that can be higher or lower for a given drug compared with the 25 percent coinsurance under the defined standard benefit. Alternatively, instead of having a deductible, a plan may use a cost-sharing rate higher than 25 percent. Once a sponsor offers at least one plan with basic benefits in a region or a service area, it may also offer a plan with enhanced benefits—basic and supplemental benefits combined, with a higher average benefit value—by including, for example, lower cost sharing, coverage for drugs filled during the gap, and an expanded drug formulary that includes non-Part D–covered drugs.[11]

In 2013, 58 percent of PDP enrollees had basic coverage that was actuarially equivalent to the defined standard benefit, most with tiered copayments. Another 39

FIGURE 14–1

PDP enrollees are less likely to have benefits in the coverage gap



Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Figures exclude employer-only plans, plans offered in U.S. territories, 1876 cost plans, special needs plans, demonstrations, and Part B–only plans. Coverage in the gap is typically restricted to a subset of formulary drugs.

Source: MedPAC analysis of CMS landscape, plan report, and enrollment data, 2006–2013.

percent of PDP enrollees had enhanced benefits—the typical enhancement being a lower deductible rather than benefits in the coverage gap. Three percent were in defined standard benefit plans. MA–PD enrollees were predominantly in enhanced plans with no deductible (Table 14-4). Enrollees in PDPs are more likely to have a deductible in their plans' benefit design than enrollees in MA–PDs, which reflects the ability of MA–PDs to use MA (Part C) rebate dollars to supplement benefits or lower premiums.[12]

The ability of MA–PDs to use Part C rebate dollars to enhance their Part D benefits affects the difference between PDPs and MA–PDs in the availability of benefits in the coverage gap (Figure 14-1). In 2013, only 7 percent of PDP enrollees (about 1.2 million beneficiaries) were in plans that offered benefits in the coverage gap beyond what is required by PPACA. However, about 37 percent of PDP enrollees received Part D's LIS, which effectively eliminated their coverage gap. By comparison, 50 percent of MA–PD enrollees (about 4.6 million beneficiaries) were in plans offering gap coverage.

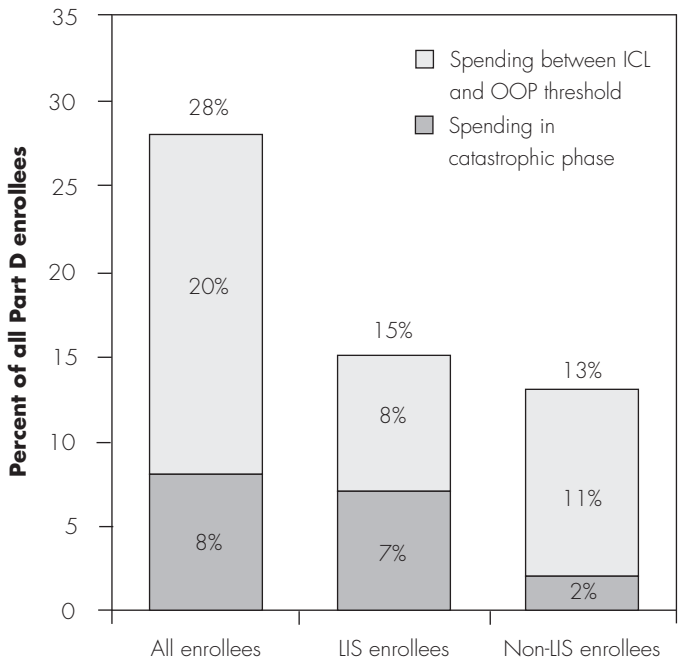
Use of Part D benefits and enrollees reaching the coverage gap

Prescription drugs are used widely by Medicare beneficiaries. According to the Commission's analysis of 2011 Part D claims data, about 92 percent of Part D enrollees filled at least one prescription during the year. Enrollees filled an average of 4.3 prescriptions per month, with considerably higher average utilization among those who received the LIS (5.1 per month) than among beneficiaries who did not (3.8 per month).

In 2011, about 28 percent of Part D enrollees had spending high enough to reach the coverage gap (Figure 14-2, p. 366). LIS enrollees accounted for more than half of the enrollees reaching the coverage gap (4.8 million, or about 15 percent of Part D enrollees). Slightly over 2.6 million, or 8.4 percent of Part D enrollees, had spending high enough to reach the catastrophic phase of the benefit. About 2 million of them (about 7 percent of Part D enrollees) received the LIS.

FIGURE 14–2

Part D enrollees with spending in the coverage gap and catastrophic phase, 2011



Note: ICL (initial coverage limit), OOP (out-of-pocket), LIS (low-income subsidy). For LIS enrollees, the cost-sharing subsidy effectively eliminates the coverage gap. In 2011, Part D enrollees reached the ICL at $2,840 in gross drug spending. If they had no supplemental coverage, an enrollee reached the annual OOP threshold at $4,550 of OOP spending or qualifying drug spending made on behalf of the beneficiary, including the 50 percent discount paid for by pharmaceutical manufacturers for brand-name drugs. Some non-LIS enrollees who reached the catastrophic phase of the benefit may have had some gap coverage.

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

Although over 80 percent of enrollees who reach the catastrophic phase of the benefit continue to be those receiving the LIS, there was a noticeable increase in the number of non-LIS enrollees who reached the catastrophic phase of the benefit in 2011—from about 400,000 in 2010 to slightly over 500,000 in 2011, or an increase of over 27 percent.

Before 2011, Part D enrollees who entered the coverage gap faced 100 percent of the plan's negotiated price for the prescriptions filled unless they were in a plan that provided some benefits in the coverage gap or were an LIS enrollee, for whom the gap is eliminated. Beginning in 2011, non-LIS enrollees see reduced cost sharing as the coverage gap is gradually phased out between 2011 and 2020 because of changes made by PPACA. Much of the increase in the number of non-LIS enrollees who reach the catastrophic phase in 2011 likely reflects the improved access to drugs as the coverage gap is phased out (see text box on effects of PPACA on drug spending and use, pp. 377–379).

Most Part D enrollees have good access to prescription drugs

Surveys indicate that beneficiaries enrolled in Part D are generally satisfied with the program and their plans (Department of Health and Human Services 2010, Keenan 2007, *Medical News Today* 2009, PRNewswire 2010, Weems 2008). Our analysis of the 2012 Consumer Assessment of Healthcare Providers and Systems® (CAHPS®) survey shows that over three-quarters of the respondents are satisfied with the drug benefit, and over 90 percent said they would recommend their plans to other people.

Most Part D enrollees appear to have good access to prescription drugs. In 2011, more than 80 percent were satisfied with the drugs listed on plan formularies and over 90 percent reported having good access to pharmacies (Table 14-5). Only 6 percent reported having had prescriptions for medications they did not obtain during the year. Cost was the main reason for not obtaining medications for all enrollees, accounting for roughly half of those who did not obtain medications. Of the 6 percent, between 25 percent and 35 percent of enrollees reported that they chose not to obtain medications because they were concerned about reactions to the medications, the medication was not necessary, or they did not think the medication would help.

Although most enrollees reported being able to obtain medications they needed, about one in five enrollees reported having experienced issues with medication costs at least some of the time. Enrollees reported taking smaller doses, skipping doses to make medication last longer, delaying or not filling a prescription, or spending less in other areas to save up for prescription drugs (Table 14-5). A higher share of LIS enrollees (27 percent) reported having experienced at least some issues with medication costs compared with non-LIS enrollees (17 percent).

Other measures of access to prescription drugs

The number of drugs that sponsors list on a formulary is one way to measure beneficiaries' access to prescription drugs. A plan's use of utilization management tools—

TABLE 14–5

Part D enrollees' access to prescription drugs, 2011

	All Part D	Plan type		Subsidy status	
		PDP	MA–PD	LIS	Non-LIS
Percent:					
Satisfied with plan list of drugs covered*	82%	80%	84%	82%	81%
Satisfied with the ease of finding pharmacy that accepts drug plan*	91	91	92	90	92
Reporting medication(s) not obtained	6	6	5	6	5
Reporting some issues with medication costs**	20	22	18	27	17

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), LIS (low-income subsidy).
*A small share of respondents refused to respond, indicated that they did not know the answer to the question, or had no experience related to the question. For the question about the plan list of drugs, that share was about 6 percent. For the question about the ease of finding a pharmacy that accepts the drug plan, the share was about 4 percent. Survey responses to these questions were classified as inapplicable to a small share of respondents, ranging from 3 percent to 5 percent.
**Includes beneficiaries who experienced any of the following: took smaller doses or skipped doses to make medication last longer, delayed filling a prescription because of cost, did not fill a prescription because of cost, or spent less in other areas to save up for prescription drugs.

Source: MedPAC analysis of 2011 Medicare Current Beneficiary Survey Access to Care file.

such as prior authorization, quantity limits, and step therapy requirements—is another way to measure access.[13] On the one hand, utilization management tools, if used appropriately, can reduce the use of inappropriate medications. On the other hand, they have the potential to limit or delay access to needed medications. These measures of access are inherently imperfect. For example, formularies that list fewer drugs could still provide adequate access to appropriate medications if plans provide coverage for unlisted drugs through the nonformulary exceptions process.

Plans are required to establish exceptions and appeals processes to ensure that their formularies do not impede access to needed medications. The relative ease or burden associated with the exceptions process varies from plan to plan. We looked into Part D's exceptions and appeals process and found insufficient data to evaluate how well the process is working for beneficiaries to gain access to needed medications. We also found that the process is complex and burdensome for many individuals (see text box, pp. 368–369).

Other factors, such as the amount of cost sharing, can significantly affect beneficiaries' access to medications, regardless of the size of the formulary. For plan sponsors, cost sharing plays an important role in attracting or retaining enrollees while managing drug use to remain competitive.

For example, cost-sharing requirements for specialty-tier drugs can be high, typically about 33 percent of the negotiated price of a drug. Under CMS's regulations, enrollees are not permitted to appeal specialty-tier cost sharing like they can for other drugs, such as those on tiers for nonpreferred brands. Because drugs on specialty tiers are often used to treat serious chronic illnesses, such as rheumatoid arthritis and multiple sclerosis, patients who need these drugs can face relatively high cost sharing for medications (until they reach the catastrophic phase of the benefit) in addition to significant OOP costs for their medical care. From a sponsor's perspective, higher priced drugs may be used more widely than the evidence of their effectiveness supports, and higher coinsurance may temper their use. Some sponsors may use a specialty tier if most of their competitors also use one to limit the risk of attracting enrollees who take very expensive drugs.

A growing number of PDPs use tiered pharmacy networks that have differential cost sharing to distinguish between preferred and nonpreferred pharmacies (see text box, pp. 370–371). The cost-sharing differential can be significant. In 2014, over 70 percent of PDPs have tiered pharmacy networks with lower cost sharing at preferred pharmacies (Hoadley et al. 2013a). The impact of the higher cost sharing at nonpreferred pharmacies, particularly for beneficiaries who are unaware of or do not understand the distinction between preferred and nonpreferred pharmacies, may be significant. We will continue to monitor the effects of tiered pharmacy networks on beneficiary access and costs.

Part D exceptions and appeals

Under Part D, an enrollee may file a request for an exception for nonformulary drugs or an exception to a tiered cost-sharing structure as long as the request is supported by medical necessity. In 2012, CMS audits found that plans had difficulties in the areas of Part D coverage determination, appeals, and grievances (Centers for Medicare & Medicaid Services 2013f). Examples of problems identified in the CMS audit included meeting mandated time frames, inappropriate denial of requests, and failure to notify the beneficiaries or their prescribers of coverage decisions (Centers for Medicare & Medicaid Services 2013b).

The Part D appeals process is complex, involving multiple levels. It begins with a denied request for an exception—either for a nonformulary drug or a tiered copayment (Figure 14-3). To initiate an appeals request, an enrollee, the enrollee's prescribing physician, or his or her authorized representative must request a redetermination from the plan. If dissatisfied with the outcome of the redetermination, the enrollee can ask for reconsideration—a review from an independent review entity (IRE). If the enrollee remains dissatisfied, he or she may appeal to an administrative law judge (ALJ), then to the Medicare Appeals Council (MAC), and finally to federal district court, as long as the amount in controversy exceeds specified dollar thresholds.[14]

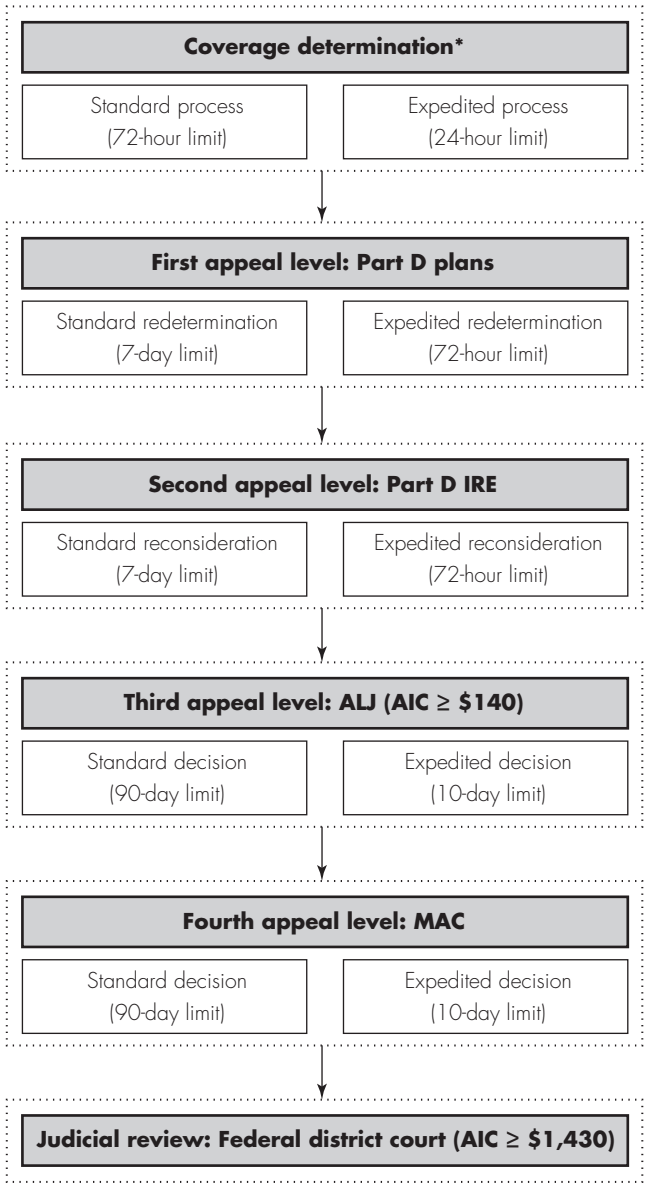
To conduct our own evaluation of the exceptions and appeals process, we examined available data and conducted focus groups and interviews with beneficiaries, physicians, and beneficiary counselors. The data that were available to us were insufficient to make a comprehensive assessment of the plans' administration of the process, and our discussions with the principal parties involved suggest the need for greater transparency and streamlining.

Need for additional data on the outcomes of the exceptions and appeals process

Although there are multiple levels of appeals, the data we had access to pertained only to the second level of the appeals process, where the plans' adverse coverage determinations are reviewed by the IRE.

FIGURE 14–3

Appeals process under Medicare Part D



Note: IRE (independent review entity), ALJ (administrative law judge), AIC (amount in controversy), MAC (Medicare Appeals Council). *A request for a coverage determination includes a request for a formulary exception or a tiering exception. A request for a coverage determination or an appeal can be submitted by an enrollee, the enrollee's prescribing physician, or the enrollee's authorized representative. AICs shown are for 2014.

(continued next page)

Part D exceptions and appeals (cont.)

Between 2006 and 2012, the number of cases that reached the IRE was less than 1 case per 1,000 enrollees in any given year. A comparable figure for the Medicare Advantage program ranged from about 3 cases per 1,000 in 2006 to about 8 cases per 1,000 enrollees in 2012. It is not clear whether the lower appeals rate observed under Part D is a cause for concern. On the one hand, the low appeals rate may reflect the differences in the nature of the services provided under the two programs. For example, beneficiaries may find alternative medications or ways to obtain needed medications outside of the exceptions and appeals process. On the other hand, the low appeals rate may reflect the lack of transparency in the appeals process or excessive administrative burdens imposed on enrollees and prescribers that discourage them from submitting an appeal.

Some trends suggest improvements in the plans' exceptions and appeals process. For example, an increase in the share of appeals upheld by the IRE (i.e., the IRE agrees with plans' coverage decisions) likely reflects improvement in the appropriateness of plans' coverage decisions. Other trends raised concerns. For example, the share of appeals that were upheld by the IRE was consistently below that observed for Medicare Advantage plans. We also found that the outcomes of the IRE review varied widely across plans in both 2012 and 2013, and some plans performed poorly in both years.

The IRE data, however, do not provide information needed to determine how well the process works for beneficiaries. We believe that providing public access to data on outcomes of the exceptions and appeals process at the plan level—coverage determinations and redeterminations—would improve the ability to assess the effectiveness of the exceptions and appeals process in ensuring access to clinically appropriate medications, as well as provide a useful metric to evaluate plan performance.

Need for increased transparency and a less burdensome process

Our focus groups with beneficiaries and physicians and interviews with beneficiary counselors revealed general confusion and frustration with the process. For example, the majority of beneficiaries were not aware that they could ask for an exception or appeal a plan decision, nor could they understand how the appeals process works. Physicians often found plan exceptions and appeals processes frustrating, noting that some plans' processes are particularly burdensome. Beneficiary counselors reported that they treated the exceptions and appeals process as a last option and often helped beneficiaries find alternative ways to access their medications—for example, by directing them to manufacturers' assistance programs. While the exceptions and appeals process must ensure that exceptions are granted only for clinically appropriate cases to protect the tools that plans use to manage the benefit, these findings suggest a need for increased transparency and streamlining of the processes involved so that beneficiaries and physicians are not discouraged from seeking exceptions for needed medications. ■

Benefit offerings for 2014

Beneficiaries will continue to have many choices of Part D plans in each region. However, each year, a subset of beneficiaries is affected by the entry and exit of plans resulting from decisions by plan sponsors or CMS not to renew contracts. Changes in business strategies also affect plan benefits that are available in a given region.

Number of plans remains stable in 2014, with an increase in PDP offerings

Between 2013 and 2014, the number of stand-alone PDPs increased by about 13 percent—from 1,031 to 1,169—while the number of MA–PDs decreased by 1 percent—from 1,627 to 1,615 (Figure 14-4, p. 372). The number of plans offered has fluctuated over the years. The largest reduction occurred between 2010 and 2011. It was primarily the result of CMS policies that were intended to differentiate more clearly between basic and enhanced

Trend toward use of tiered pharmacy networks

Part D plans contract with pharmacies to fill prescriptions for their enrollees. Plans are required to contract with any pharmacy that agrees to the terms of the contract. However, pharmacies may choose not to do business with the plan. Any pharmacy that contracts with a drug plan is considered to be in the plan's network, whereas any others are considered out of network.

In general, plans do not cover drugs bought from out-of-network pharmacies. Exceptions may include the following: (1) the beneficiary cannot reasonably be expected to obtain such drugs at a network pharmacy, and (2) the beneficiary does not access Part D–covered drugs at an out-of-network pharmacy on a routine basis. In such situations, the plan must cover the prescription but can require higher cost sharing—for example, by requiring the beneficiary to pay the difference in the price the plan would pay to an out-of-network pharmacy compared with an in-network pharmacy. To ensure that beneficiaries have adequate access to in-network pharmacies, plans are required to meet the statutorily defined network adequacy requirement.[15] Because of these restrictions, plans' networks are usually wide. In 2013, about 80 percent of prescription drug plans (PDPs) contracted with over 95 percent of pharmacies in their respective regions. In most regions, even the plan with the smallest network included at least 90 percent of pharmacies in its network. Only two plans, both issued by the same company, listed less than 70 percent of the pharmacies in their area as in network (NORC at the University of Chicago 2013).

In-network pharmacies can be further classified as preferred or nonpreferred pharmacies. (Network adequacy for plans with preferred and nonpreferred pharmacies is based on access to both types of pharmacies since they are all considered in network.) While the medicines covered by all in-network pharmacies must be the same, the corresponding cost-sharing amounts may depend on the classification of the pharmacy within the plan's network.

(continued next page)

TABLE 14–6 **Enrollment in PDPs with preferred and nonpreferred pharmacies, 2013**

	Number of regions offered	Share of all PDP enrollment	Average share of pharmacies that the plan lists as preferred
AARP MedicareRx Enhanced	32	0.7%	27.5%
AARP MedicareRx Preferred	34	21.4	27.4
AARP MedicareRx Saver Plus	30	2.9	27.4
Aetna CVS/Pharmacy Prescription Drug Plan	29	2.5	13.4
First Health Part D Value Plus	32	3.5	32.8
Humana Enhanced	34	7.3	23.7
Humana Walmart-Preferred Rx Plan	34	9.7	9.4
SilverScript Choice	33	1.9	43.8
SilverScript Plus	33	1.0	43.8
United American–Select	33	0.8	25.7
Other*	varies	1.7	14.1–95.7
Total		53.4	29.7

Note: PDP (prescription drug plan). Average share of pharmacies is weighted by the number of pharmacies in each region and includes only regions in which the plan is offered.
*Includes both national plans—such as SmartD Rx—offered in all 34 regions, and non-national plans—such as Health Alliance Medicare Prescription Plan–Basic—offered in one region. Each of the plans in the "other" category accounts for less than 0.5 percent of total PDP enrollment.

Source: NORC/Social & Scientific Systems analysis for MedPAC of formularies submitted to CMS.

Trend toward use of tiered pharmacy networks (cont.)

In recent years, a growing number of plan sponsors have chosen to offer preferred pharmacies in their network, with potentially significant price differentials for beneficiaries. In 2012, 14 percent of PDPs, representing 13 percent of total PDP enrollment, used preferred pharmacy networks. One year later, 46 percent of PDPs (over 50 percent of PDP enrollment) had developed preferred pharmacy networks.[16]

With an increasing number of plans using tiered pharmacy networks (nearly 70 percent of PDP offerings in 2014), CMS has raised concerns about the potential effect on program costs. CMS requires that plan sponsors offering reduced cost sharing at a preferred pharmacy relative to a nonpreferred pharmacy must do so without increasing CMS payments to the plans (Centers for Medicare & Medicaid Services 2011a). When CMS examined the negotiated prices for the 50 most frequently prescribed drugs, it found that, during the month of March in 2012, prices were higher at preferred pharmacies for about one-third of the PDP contracts (accounting for about 11 percent of PDP enrollees) they examined, potentially increasing program costs (Centers for Medicare & Medicaid Services 2013e).[17]

In 2013, plan offerings with preferred networks include some of the largest plans in Part D, such as AARP MedicareRx Preferred and Humana Walmart-Preferred Rx plan. Plans with preferred networks accounted for slightly over 53 percent of PDP enrollment (Table 14-6). For the majority of such plans, no more than one-third of in-network pharmacies are preferred (i.e., have the lowest cost-sharing amounts).

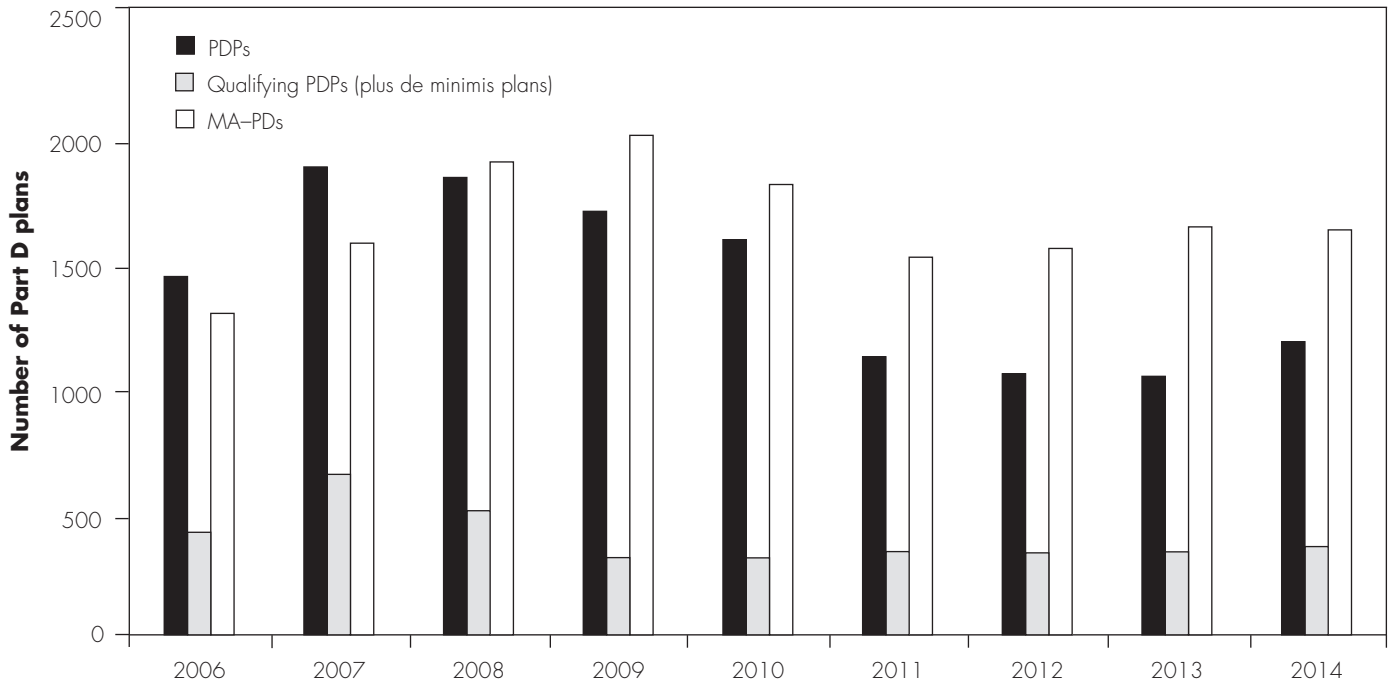
The share of pharmacies on plans' preferred lists can vary dramatically from one plan offering to another (Table 14-6). The two plan offerings that have the smallest preferred networks are cobranded with a pharmacy chain (Aetna CVS and Humana Walmart). Most of the plans are not cobranded with a pharmacy chain and often have preferred pharmacies from more than one pharmacy chain. For example, First Health Part D Value Plus listed pharmacies in the Target, Walgreens, Kmart, and Walmart chains as preferred. These chain pharmacies combined, on average, accounted for about one-third (32.8 percent) of the pharmacies in regions served by the plan.

CMS rules establish that the viability of a pharmacy network with preferred and nonpreferred pharmacies is conditional on cost sharing that is not "so significant as to discourage enrollees in certain areas (rural areas or inner cities, for example) from enrolling in that Part D plan" (Centers for Medicare & Medicaid Services 2011b). Different plans have interpreted this rule in different ways, with some plans using much stronger incentives than others for their enrollees to use preferred pharmacies. For example, the cost-sharing differential between preferred and nonpreferred pharmacies in the Humana Enhanced plan is only a few dollars for generics and no difference for brand tiers. By contrast, cost sharing is at least $10 more for every tier of the two SmartD Rx plans if an enrollee uses a nonpreferred pharmacy.[18] ■

benefit plans and to discourage plans with low enrollment.[19] In 2014, beneficiaries continue to have many plans to choose from, ranging from 28 PDP options in Alaska to 39 PDP options in the Pennsylvania–West Virginia region, along with MA–PD options in most areas of the country. The number of MA–PDs available to a beneficiary varies by the county of residence, with a typical county having between 3 and 10 MA–PD plans to choose from. A handful of counties have no MA–PD plans available.

In 2014, 352 PDPs are available to LIS enrollees with no premium, up from 331 in 2013 (Figure 14-4, p. 372).[20] All regions continue to have many premium-free plans available, ranging from four plans in Nevada and Hawaii to 15 plans in the Indiana–Kentucky region. About 1.9 million LIS enrollees were in plans that did not qualify as premium free in 2013 (Hoadley et al. 2013a). As of December 2013, CMS estimated that it will have reassigned about 500,000 LIS enrollees to different plans because their previous plan's premium did not fall below the 2014 threshold.[21] LIS enrollees who selected a plan that differed from their randomly assigned plan are not reassigned. CMS sends letters to those LIS enrollees

FIGURE 14–4 Number of Part D plans remains stable between 2013 and 2014



Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Qualifying PDPs are plans for which low-income subsidy (LIS) enrollees pay no premium because the plans' premiums are at or below a regional premium threshold. De minimis plans are plans that CMS permitted to retain their LIS enrollees because the plan premium was within a certain variance of the regional LIS premium threshold. The figures exclude employer-only plans, plans offered in U.S. territories, 1876 cost plans, special needs plans, demonstrations, and Part B–only plans.

Source: CMS landscape and plan report files, 2006–2014.

about premium-free plan options that are available in their regions.

Notable changes for 2014 in benefit offerings

Beneficiaries are encouraged to reexamine their plan options from time to time. In addition to the annual change in plan availability and premiums charged, most plans make some changes annually to their benefit offerings—such as deductible amounts and plan formularies—that can directly affect access to and affordability of medications. For the 2014 benefit year, the structure of drug benefits for MA–PDs is holding fairly steady, while there were some notable changes for stand-alone PDPs.

Fewer PDPs are offering coverage in the gap

In 2014, fewer PDPs than in 2013 are offering coverage in the gap beyond that required by PPACA—21 percent compared with 34 percent. In 2014, about three-quarters of PDPs that offer gap coverage include some brand-name drugs. By contrast, the share of MA–PDs with gap coverage is holding steady at about 50 percent in 2014. Among MA–PDs that offer gap coverage in 2014, a slightly smaller share than in 2013 include some brand-name drugs in the coverage gap (51 percent compared with 55 percent).

The extent of coverage in the gap varies from plan to plan. In 2014, about 80 percent of the PDPs that offer brand coverage in the gap provide coverage for between 10 percent and 65 percent of brand-name drugs listed on the formulary. In comparison, most of the brand coverage among MA–PDs includes only a few brand-name drugs, typically less than 10 percent of brand-name drugs listed on the formulary.

The reduction in the number of PDPs offering gap coverage may be due in part to the changes made by PPACA to gradually phase out the coverage gap. In 2014, the basic Part D benefit will cover 28 percent of the cost of generic drugs and 2.5 percent of the cost of brand-

TABLE 14–7 **2014 formularies for stand-alone PDPs with highest 2013 enrollment**

Stand-alone PDPs with the highest 2013 enrollment	Enrollment, 2013 (in millions)	Percent of drugs on formulary		Percent of formulary drugs with any utilization management*	
		2013	2014	2013	2014
AARP MedicareRx Preferred	3.8	92%	92%	21%	23%
SilverScript Basic**	2.8	77	N/A	40	N/A
Humana Preferred Rx Plan	1.8	83	80	48	48
Humana Enhanced	1.3	89	89	49	50
AARP MedicareRx Saver Plus	0.8	83	83	19	25
First Health Part D Value Plus	0.7	80	78	40	41
First Health Part D Essentials	0.7	79	78	31	40
Cigna Medicare Rx Secure	0.7	86	85	33	38
WellCare Classic	0.6	74	73	34	38

Note: PDP (prescription drug plan), N/A (not available). Enrollment figures are for October 2013 and exclude employer group plans and territories. The number of drugs on the formulary for 2013 is 1,174; for 2014, the number is 1,233.
*Utilization management includes the use of prior authorization, quantity limits, and step therapy requirements.
**Not all formulary information for SilverScript plans were available at the time of this analysis was conducted. SilverScript plans were placed under CMS sanction in 2013 and were prohibited from accepting new enrollment during the 2014 annual open enrollment period.

Source: NORC/Social & Scientific Systems analysis for MedPAC of formularies submitted to CMS.

name drugs in the gap phase. The 50 percent discount paid for by pharmaceutical manufacturers for brand-name drugs further reduces beneficiaries' cost sharing for brand-name drugs to about 47.5 percent.[22] The increased generosity of the basic benefit may be replacing some of the supplemental benefits provided during the gap phase of the benefit.

More than half of PDPs continue to charge a deductible in 2014. Among PDPs with a deductible, in 2014 the trend is away from charging a deductible below the standard amount ($310)—only 4 percent of the plans charge a lower deductible, compared with over 10 percent during the last few years. As in previous years, a much higher share of MA–PDs have no deductible (82 percent) compared with PDPs (47 percent).

Continued widespread use of utilization management tools

The use of utilization management tools in Part D—including quantity limits, step therapy, and prior authorization—has grown over the years. Sponsors use such tools for drugs that are expensive, potentially risky, or subject to abuse, misuse, and experimental use. Such tools are also often used to encourage the use of lower cost therapies.

Under contract with the Commission, researchers from NORC at the University of Chicago and from Social & Scientific Systems analyzed Part D formulary data for 2014. For this analysis, drugs are defined at the level of chemical entities—a broad grouping that encompasses all of a chemical's forms, strengths, and package sizes—that combine brand-name and generic versions of specific chemicals (Medicare Payment Advisory Commission 2008).

For the nine largest nationwide PDPs, which accounted for nearly 60 percent of the PDP enrollment in 2013, the shares of drugs (technically, all distinct chemical entities) listed on their formularies remained stable or saw a modest decrease of 3 percentage points or less between 2013 and 2014 (Table 14-7).[23]

The use of utilization management increased for seven out of the nine largest PDPs, with many plans requiring some type of utilization management on more than one-third of drugs listed on their formularies. The most common strategy that plans use to manage enrollees' drug use is to apply a prior authorization requirement. In 2014, about 20 percent of formulary drugs are subject to prior authorization. Among the top nine PDPs, those operated by Humana Inc. (Humana Preferred Rx Plan and Humana

TABLE 14–8 **2014 cost-sharing amounts for stand-alone PDPs with highest 2013 enrollment**

Stand-alone PDPs with the highest 2013 enrollment	Enrollment, 2013 (in millions)	Generic		Preferred brand		Nonpreferred brand		Specialty	
		2013	2014	2013	2014	2013	2014	2013	2014
AARP MedicareRx Preferred	3.8	$3/$5	$3/$6	$40	$40	$85	$85	33%	33%
SilverScript Basic	2.8	$2	$2	23.5%	20%	45%	42%	25%	25%
Humana Preferred Rx Plan	1.8	$1/$4.5	$1/$2	20%	20%	35%	35%	25%	25%
Humana Enhanced	1.3	$2/$5	$2/$5	$41	$42	$90	$92	33%	33%
AARP MedicareRx Saver Plus	0.8	$1/$2	$1/$2	$25	$20	$45	$35	25%	25%
First Health Part D Value Plus	0.7	$1	$3/$11	25%	$37	45%	$88	N/A	33%
First Health Part D Essentials	0.7	$1	$1	25%	15%	45%	45%	N/A	N/A
Cigna Medicare Rx Secure	0.7	$0/$8	$0/$3	$30	$30	$80	$65	25%	25%
WellCare Classic	0.6	$6	$0/$15	$42	$40	$94	$94	33%	33%

Note: PDP (prescription drug plan). Enrollment figures are for October 2013 and exclude employer plans and territories. In cases where plans vary cost-sharing amounts across regions, we report unweighted median cost-sharing amounts.

Source: NORC/Social & Scientific Systems analysis for MedPAC of formularies submitted to CMS.

Enhanced) have the highest share of drugs with utilization management.

Modest increase in cost-sharing requirements

Cost-sharing requirements have generally been rising over the years. In 2014, changes in cost-sharing requirements for the top nine nationwide PDPs are modest for the most part, with a few notable exceptions. For example, some enrollees in First Health Part D Value Plus may experience significant change in their OOP spending, depending on the medications they take because cost sharing for brand-name drugs changes from coinsurance to copayments and some drugs are on the new specialty tier with a 33 percent coinsurance (Table 14-8). Of the top nine PDPs, only one plan—First Health Part D Essentials—does not have a specialty tier.

The relative stability of the copayments and coinsurance amounts from year to year observed for many plans is primarily due to the requirement that benefit offerings remain actuarially equivalent to the defined standard benefit and to CMS's systematic review of plan benefit packages. During the review process, CMS identifies, for example, outlier plans and requires them to bring the cost-sharing amounts in line with those of other plans.

More plans are using a five-tier formulary structure

In 2014, seven of the top nine PDPs are using a five-tier formulary structure that includes two tiers for generic drugs (preferred and nonpreferred), two tiers for brand drugs, and a tier for specialty drugs. Many plans are keeping their generic cost sharing low, with the exception of two plans—First Health Part D Value Plus and WellCare Classic. Both plans have moved from having a single generic tier to two generic tiers and have set a relatively high copayment for the nonpreferred generic tier ($11 and $15, respectively); by comparison, nonpreferred generic cost sharing for the other five plans using a five-tier formulary structure ranges from $2 to $6 (Table 14-8).

The widespread use of a nonpreferred generic tier in 2014 is a dramatic shift from earlier years when we began to see some plans use a nonpreferred generic tier in their formulary for a limited number of drugs. In 2014, the majority of the PDPs that have two generic tiers are placing the majority of the covered generic drugs on the nonpreferred tier (on average, about three-quarters of generic drugs on plan formularies).[24]

A broader use of lower generic cost-sharing amounts and higher cost-sharing amounts on nonpreferred generic tiers both have the potential to lower the overall program costs by encouraging enrollees to use lower priced products. That may not be the case for LIS enrollees, for whom the difference between those amounts and the statutorily set amounts (between $0 and $2.55 in 2014, depending on the subsidy level) are picked up by Part D's low-income cost-sharing subsidy (about 4 percent of enrollees in First Health Part D Value Plus and nearly 70 percent of

enrollees in WellCare Classic in 2013). Thus, higher cost sharing on a nonpreferred generic tier may result in higher program spending for the subsidy.

Costs of Part D

To monitor Part D's costs, we examine aggregate program spending, per capita spending, trends in the prices at the pharmacy counter, and trends in plans' bid amounts. Total program spending continues to grow at a faster rate than the growth in Part D enrollment. The "excess" growth appears to be driven in large part by growth in the average price of drugs filled, particularly among enrollees receiving the LIS. As in the past, we find that drug utilization for Part D enrollees with high spending was driving faster growth for some components of Part D spending than others. Moreover, we find that changes made by PPACA to phase out the coverage gap may have increased the number of enrollees with high spending.

In this section, we present data on Part D spending that we use to understand the sources of the "excess" growth. We also provide an updated analysis of the patterns of drug use for Part D enrollees with high spending to understand the sources of spending growth and the effects of PPACA on Part D program costs (see text box on effects of PPACA on drug spending and use, pp. 377–379).

Aggregate program costs

Medicare pays plan sponsors three major subsidies on behalf of each plan enrollee:

- ***Direct subsidy*—**Medicare makes a monthly payment to plans, which is set as a share of the national average bid for Part D basic benefits, adjusted for the risk of the individual enrollee.
- ***Reinsurance*—**Medicare subsidizes 80 percent of drug spending above an enrollee's annual OOP threshold. Reinsurance reduces risk for Part D sponsors by providing greater federal subsidies for the highest cost enrollees.
- ***LIS*—**Medicare pays the plan to cover expected cost sharing and premiums for enrollees eligible for the subsidy.

Direct and reinsurance subsidies combined cover 74.5 percent of the cost of basic Part D benefits, on average.[25] In addition to these subsidies, Medicare establishes symmetric "risk corridors" separately for each plan to limit its overall losses or profits. Under risk corridors, Medicare finances a portion of costs that are higher than expected or recoups a portion of profits that are higher than expected.

Payments to plans grew faster than enrollment, with the low-income subsidy as the single largest component

Between 2007 and 2012, Part D program spending (including spending for the RDS) grew from $46.7 billion to $62.5 billion (Table 14-9, p. 376). In 2012, the total was made up of $20.9 billion in direct subsidy payments to plans, $15.6 billion in payments for individual reinsurance, $22.6 billion for the LIS, and $3.3 billion in RDS payments (Boards of Trustees 2013). Payments to plans for the three subsidies (not including the RDS) grew by 38 percent during this period, exceeding the Part D enrollment growth (29 percent) by 9 percentage points.

In 2012, LIS payments continued to be the largest component of Part D spending. Moreover, because these individuals tend to use more medications than other Part D enrollees, a disproportionate share of spending for the direct subsidy and individual reinsurance also reflects benefits for LIS enrollees.

Phase-out of the coverage gap likely contributing to the growth in spending for individual reinsurance

Medicare payments for individual reinsurance have grown considerably faster than other components of Part D spending, increasing at an average annual rate of 14 percent between 2007 and 2012, compared with 6 percent for overall Part D spending. Payments for individual reinsurance grew by 13 percent between 2011 and 2012, a rate much higher than the growth rates for direct subsidy payments (4.2 percent) and for LIS payments (about 1.3 percent) (Table 14-9, p. 376).

Multiple factors likely contribute to the growth in reinsurance spending. Our previous analysis of drug spending for and use by enrollees with spending high enough to reach the benefit's catastrophic phase showed that spending was driven primarily by the volume of prescriptions filled by these enrollees and by their tendency to use more brand-name medications than enrollees who do not incur high drug spending. We also found that many of the therapies used by the high-cost beneficiaries were in therapeutic classes that had generic alternatives that would have cost significantly less than

TABLE 14–9 **Medicare's reimbursement amounts for Part D**

	2007	2008	2009	2010	2011	2012
In billions of dollars						
Direct subsidy	$18.1	$17.7	$18.9	$19.7	$20.1	$20.9
Reinsurance	8.0	9.4	10.1	11.2	13.8	15.6
Low-income subsidy	16.7	18.0	19.6	21.0	22.3	22.6
Retiree drug subsidy	3.9	3.8	3.9	3.9	3.6	3.3
Total	$46.7	$48.9	$52.4	$55.8	$59.8	$62.5
Annual percentage change						
Direct subsidy	2.7%	–2.0%	6.5%	4.5%	1.8%	4.2%
Reinsurance	33.0	17.8	7.1	10.7	23.3	13.3
Low-income subsidy	11.0	7.5	8.6	7.5	6.2	1.3
Retiree drug subsidy	2.5	–3.5	3.2	0.4	–6.9	–8.4
Total	9.9	4.7	7.1	6.5	7.1	4.4

Note: The numbers above reflect reconciliation amounts. Most enrollees paid premiums directly to Part D plans, and those amounts are not included above. On a cash basis, the Boards of Trustees estimates that premiums paid by enrollees totaled $4.1 billion in 2007, $5 billion in 2008, $6.1 billion in 2009, $6.7 billion in 2010, $7.3 billion in 2011, and $7.8 billion in 2012. Totals may not sum due to rounding.

Source: MedPAC based on Table IV.B10 of the 2013 annual report of the Boards of Trustees of the Medicare trust funds.

their brand-name counterparts, rather than higher priced products that had few or no therapeutic substitutes (Medicare Payment Advisory Commission 2012).

Our analysis of 2010 and 2011 Part D claims data shows that these findings still hold true. Less than 10 percent of enrollees with high drug spending used biologics, and spending on biologics accounted for 6 percent to 7 percent of drug spending for these beneficiaries, a rate similar to those observed in 2009.[26] They also tended to use more brand-name products—about 40 percent compared with about 20 percent for other enrollees. This pattern of drug use generally held true for many therapeutic classes with generic alternatives. For example, among diabetic therapies, brand-name drugs accounted for 62 percent of the prescriptions filled by high-cost enrollees, compared with slightly over 30 percent for other enrollees. Finally, two changes made by PPACA likely contributed to the even higher growth for reinsurance payments between 2010 and 2011 by increasing the number of enrollees who reach the benefit's catastrophic phase (see text box, opposite page).

Another factor that may contribute to the faster growth in spending for individual reinsurance is the manner in which manufacturer rebates are allocated across the different phases of the benefit—i.e., deductible phase, initial benefit phase, coverage gap phase, and the catastrophic phase—in the plan bids and during reconciliation. However, we do not have access to the rebate data to understand how rebate allocation may be affecting the differential growth in program components.

Decrease in retiree drug subsidy payments likely to continue

The number of Medicare beneficiaries who received primary prescription drug coverage through former employers has been decreasing, from over 7 million in 2006 to about 3 million in 2013 (Boards of Trustees 2013). Employers no longer offering drug coverage to their retirees typically move their Medicare-eligible members to Part D. Enrollment in employer group plans (800 series plans) went up by about 2.3 million (mostly in PDPs) during the first three months of 2013.

The change in the tax treatment of the RDS payments is likely to have accelerated the decline in the number of beneficiaries receiving prescription drug coverage through former employers. Before 2013, the subsidy provided employers with two tax advantages. First, the RDS

Effects of PPACA on drug spending and use

The Patient Protection and Affordable Care Act of 2010 (PPACA) gradually phases out the coverage gap by reducing beneficiary cost-sharing amounts until it reaches 25 percent in 2020. For brand-name drugs, the reduction in cost sharing is achieved with a combination of a manufacturer discount that covers 50 percent of the cost of drugs for enrollees in the coverage gap and an increase in Part D's coverage of costs between 2013 and 2020.

PPACA changes involving manufacturer discounts and their application to the out-of-pocket (OOP) spending threshold are expected to increase the number of enrollees who reach the catastrophic phase of the benefit (high-cost enrollees). Beginning with the 2011 benefit year, manufacturer discounts for brand-name drugs filled during the coverage gap reduces by half the beneficiary cost sharing for brand-name drugs paid by non–low-income subsidy (LIS) enrollees. These manufacturer discounts count toward the OOP threshold, so that individuals taking brand-name medications will reach the catastrophic phase of the benefit without having spent the full amount specified by the OOP threshold. Data on program spending shows that payments for individual reinsurance grew by 23 percent between 2010 and 2011, a much higher rate than observed in most other years (Table 14-9). Much of that accelerated growth is likely due to the start of the manufacturer discount program.

More non-LIS enrollees reaching the catastrophic phase of the benefit in 2011

Our analysis of Part D claims data between 2010 and 2011 shows that the number of high-cost enrollees grew by 12 percent (Table 14-10). The increase was 9 percent (about 176,000) for LIS enrollees and 28 percent (slightly over 100,000) for non-LIS enrollees. This increase is in contrast to the period before 2011, when the numbers stayed about the same. Although multiple factors can affect the number of people reaching the catastrophic phase of the benefit, the PPACA changes likely account for much of the increase among non-LIS enrollees during this period.

Growth in spending for high-cost enrollees in 2011 driven by more enrollees reaching the catastrophic phase

A comparison of drug utilization patterns before and after PPACA's implementation shows that the accelerated growth after the change was driven primarily by the increase in the number of people reaching the benefit's catastrophic phase. Total drug spending by high-cost enrollees grew by 19 percent after the change compared with slightly less than 7 percent growth before the change. The number of

(continued next page)

TABLE 14–10 **Part D enrollees reaching the catastrophic phase of the benefit, 2007–2011**

						Average annual percent change	
	2007	2008	2009	2010	2011	2007–2010	2010–2011
Enrollees (in millions)	2.3	2.4	2.4	2.4	2.6	1%	12%
By subsidy status							
LIS	1.9	2.0	2.0	2.0	2.1	1	9
Non-LIS	0.4	0.4	0.4	0.4	0.5	–2	28

Note: LIS (low-income subsidy). Growth rates are calculated using figures before rounding is applied.

Source: Data for 2007 and 2008 are based on published figures from CMS. Data for 2009 to 2011 are based on the Commission's analysis of Part D prescription drug event data.

Effects of PPACA on drug spending and use (cont.)

prescriptions also grew much faster after the change—slightly over 11 percent compared with no growth before the change (Table 14-11). Once the changes in the average costliness of each prescription (6.8 percent for the 2009 to 2010 period and 7.1 percent for the 2010 to 2011 period) are taken into account, the growth in both spending and prescriptions filled are nearly identical to the growth in the number of people reaching the catastrophic phase of the benefit during the 2009 to 2011 period.

Following the PPACA changes, growth in drug spending and use for high-cost enrollees far outpaced that for both LIS and non-LIS enrollees, but the difference was more pronounced for the non-LIS enrollees. Between 2010 and 2011, total drug spending for non-LIS enrollees grew by nearly 38 percent compared with slightly less than 15 percent for LIS enrollees (Table 14-12). Growth in prescriptions filled generally followed the changes in the number of high-cost enrollees for both LIS and non-LIS enrollees.

There were some concerns that the manufacturer discounts reducing beneficiary OOP costs for brand-name drugs could affect enrollees' choice of brand versus generic medications, particularly if beneficiaries expected to have drug spending high enough to put them in the catastrophic phase of the benefit. However, our preliminary analysis of 2011 Part D data does not suggest a noticeable shift toward the use of brand-name medications. Between 2009 and 2011, the average generic use rate among high-cost enrollees increased from 58 percent to 63 percent, with similar increases for both LIS and non-LIS enrollees. For many of the drug classes we analyzed, the generic use rates were unchanged or higher in 2011 compared with 2009 or 2010 for both LIS and non-LIS enrollees.

Should the manufacturer discount count toward the OOP threshold?

Of the roughly 500,000 non-LIS enrollees who reached the catastrophic phase of the benefit in 2011, only 6 percent (about 30,000) met the OOP limit ($4,550 in 2011) with their actual OOP alone. These enrollees, on average, incurred about $60,000 in gross spending, with manufacturer discounts covering less than 3 percent of that total (about $1,600). Their OOP spending averaged about $5,400, and the remainder (about $53,000) was covered by the benefit.

(continued next page)

TABLE 14–11 **Part D spending and utilization by high-cost enrollees, 2009–2011**

				Annual percent change	
	2009	2010	2011	2009–2010	2010–2011
Enrollees (in millions)	2.4	2.4	2.6	–0.8%	12.1%
Aggregate utilization					
Gross spending (in billions)	$29.2	$31.2	$37.1	6.8	19.1
Prescriptions (in millions)	264.3	264.3	294.0	0.0	11.2
Average prescriptions per enrollee	111	112	111	0.8	–0.8
Average spending per prescription	$110	$118	$126	6.8	7.1

Note: Growth rates are calculated using figures before rounding is applied.

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

Effects of PPACA on drug spending and use (cont.)

TABLE 14–12

Growth in drug spending and utilization for high-cost enrollees by LIS status, 2009–2011

				Annual percent change	
	2009	2010	2011	2009–2010	2010–2011
Gross spending (in billions)					
LIS enrollees	$23.9	$25.5	$29.3	6.8%	14.9%
Non-LIS enrollees	5.3	5.7	7.8	7.1	37.7
Prescriptions (in millions)					
LIS enrollees	222.0	223.6	242.3	0.7	8.3
Non-LIS enrollees	42.3	40.7	51.7	–3.9	27.2

Note: LIS (low-income subsidy). Growth rates are calculated using figures before rounding is applied.

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

In contrast, gross spending averaged about $12,500 among the 475,000 enrollees who met the OOP limit with the combination of their own OOP spending and the manufacturer discounts. If manufacturer discounts were not treated as OOP for the purpose of determining when enrollees met the OOP threshold, they most likely would not have reached the catastrophic phase as quickly, and some likely would not have reached the catastrophic phase of the benefit in 2011. For these enrollees, manufacturer discounts covered, on average, 13 percent of their gross drug spending (about $1,600). About 40 percent of the spending ($2.4 billion) was for drugs filled after the enrollees met the OOP limit, resulting in $1.9 billion in Medicare's payments for individual reinsurance for these enrollees (80 percent of the $2.4 billion). ■

payments were and continue to be nontaxable income for employers. Second, employers had been allowed to treat the prescription drug expenses for which they receive the subsidy as a tax-deductible cost of doing business, making these subsidies worth more to the employers than the actual subsidy amounts paid. As of 2013, PPACA no longer allows employers to deduct expenses for which they receive the subsidy.

Per capita spending and use

Between 2007 and 2011, the most recent years for which we have data, the average per capita spending for Part D–covered drugs grew at an average annual rate of 3 percent, or by about 12.5 cumulatively. Growth in average per capita spending slowed in 2010 to about 1.5 percent—a trend consistent with that of general drug costs measured in national health expenditures—but picked up in 2011 (3.2 percent).

Per capita spending for LIS enrollees growing faster than for non-LIS enrollees

Spending for non-LIS enrollees remained relatively flat compared with LIS enrollees (average annual growth rate of 1.8 percent compared with 4.8 percent), resulting in a larger difference in per capita spending between the two groups—from $145 in 2007 to nearly $200 per member per month in 2011 (Table 14-13, p. 380). The growth in the number of prescriptions filled by LIS and non-LIS enrollees was comparable during this period, while the change in average price per prescription was not. Between 2007 and 2011, the average price per prescription filled by LIS enrollees grew cumulatively by about 10 percent compared with a decrease of about 2 percent for non-LIS enrollees. The mix of drugs, which may reflect differences in medication needs, can have significant effects on the cost of medications. For example, our analysis of Part D prices shows that the average price of generic products fell

TABLE 14–13 **Average per capita spending and use per month for Part D–covered drugs, 2007–2011**

	Part D spending and utilization per enrollee						
	Average spending/utilization					AAGR, 2007–2011	
	2007	2008	2009	2010	2011	In dollars	In percent
Average spending							
All Part D	$212	$221	$228	$231	$239	$7	3.0%
By LIS status							
LIS	301	324	339	348	364	16	4.8
Non-LIS	156	159	163	163	167	3	1.8
By plan type							
PDP	239	250	260	265	274	9	3.5
MA–PD	151	162	169	172	178	7	4.2
Average number of prescriptions						Number of prescriptions	
All Part D	3.9	4.1	4.1	4.2	4.3	0.1	2.1%
By LIS status							
LIS	4.6	4.9	5.0	5.1	5.1	0.1	2.6
Non-LIS	3.4	3.6	3.6	3.7	3.8	0.1	2.6
By plan type							
PDP	4.1	4.3	4.4	4.4	4.5	0.1	2.0
MA–PD	3.4	3.6	3.7	3.8	3.9	0.1	3.1

Note: AAGR (average annual growth rate), LIS (low-income subsidy), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Part D prescription drug event (PDE) records are classified into plan types based on the contract identification on each record. For purposes of classifying the PDE records by LIS status, monthly LIS eligibility information in Part D's denominator file was used. Estimates are sensitive to the method used to classify PDE records according to each plan type and LIS status. Gross drug spending includes all payments to pharmacies, including payments by drug plans, Medicare's LIS, and beneficiary out-of-pocket. Prescriptions are standardized to a 30-day supply.

Source: MedPAC analysis of Medicare Part D PDE data and denominator file from CMS.

by over 40 percent during this period, while the average price of brand products grew by between 40 percent and 60 percent between 2007 and 2011 (see section on Part D prices).

Although the growth in per capita drug spending among MA–PD enrollees was greater than for stand-alone PDP enrollees (4.2 percent compared with 3.5 percent), the average growth was lower for MA–PD enrollees in terms of the dollar increase ($7 compared with $9). Despite the higher growth rates observed, average per capita spending for MA–PD enrollees was consistently lower than that for stand-alone PDP enrollees—by around $90 per member per month.

Part D drug prices

Most plan sponsors do not negotiate drug prices directly with pharmaceutical manufacturers. Instead, sponsors engage in two separate negotiations:

- The first involves pharmacies or a network of pharmacies negotiating the prices the plan will pay the pharmacy for drug ingredient costs and dispensing fees.
- The second involves negotiating the terms under which manufacturers pay retrospective rebates.

Between 2006 and 2011, the average manufacturer rebate as a percentage of total prescription drug costs increased from less than 9 percent to 11.5 percent (Boards of

Trustees 2013). In general, plan sponsors do not receive rebates from manufacturers of generic drugs, which accounted for over three-quarters of the prescriptions dispensed under Part D in 2011. The CMS Office of the Actuary reports that "many brand-name prescription drugs carry substantial rebates, often as much as 20–30 percent" but expects the rebates to decrease as some of the drugs with the highest Part D rebate amounts lose patent protection in the next several years (Boards of Trustees 2013). Plan sponsors tend to use rebate revenues to offset plans' benefit spending (reducing plan premiums) rather than lowering the price of prescriptions at pharmacies. As a result, drug prices measured in this section do not reflect the outcomes of the rebate negotiations.

Part D plan sponsors have had mixed success at influencing drug prices. They have been successful at encouraging enrollees to use generic alternatives when available (Congressional Budget Office 2010, Office of Inspector General 2007) (see text box, p. 383). Plan sponsors regularly use cost-sharing differentials to encourage enrollees to use lower priced products such as generic drugs and brand-name drugs placed on preferred brand tiers. But sponsors have had less success at controlling the growth in prices for unique drugs and biologic products.

To track drug prices, the Commission contracted with researchers at Acumen, LLC to construct a series of volume-weighted price indexes. The indexes do not reflect retrospective rebates from manufacturers but rather the prices sponsors and beneficiaries pay to pharmacies at the point of sale (including ingredient costs and dispensing fees).

Enrollees' use of generic drugs have kept Part D prices stable

Measured by individual national drug codes (NDCs), Part D drug prices rose between 2006 and 2011 by an average of 29 percent cumulatively (Figure 14-5, p. 382).[27] At the same time, Part D sponsors have had success in encouraging enrollees to switch from brand-name drugs to generic substitutes. As measured by a price index that takes this substitution into account, Part D prices grew cumulatively by 3 percent.[28]

For most drug classes, CMS requires plan formularies to cover—in every therapeutic class and key drug type—at least two drugs that are not therapeutic substitutes, unless only one drug is approved for that class. This policy is intended to allow competition in classes with multiple products while protecting beneficiaries who need a drug that is the only one available to treat a certain condition. For six drug classes, CMS requires Part D plans to cover "all or substantially all" drugs in the class (protected class). Those classes are antineoplastics, antidepressants, antipsychotics, antiretrovirals, anticonvulsants, and immunosuppressants used by transplant patients.[29] Although plans can charge higher cost sharing for drugs in these classes—for example, by placing them on tiers for nonpreferred brands—plans may have limited ability to influence use of these classes of drugs.

As measured by individual NDCs, prices for drugs in the six protected classes showed a trend between 2006 and 2011 similar to that for all Part D drugs, rising by a cumulative 28 percent (Figure 14-5, p. 382). This growth was influenced heavily by two classes of drugs: (1) antidepressant medications, which accounted for about half of the volume in the six classes and had many generics on the market during this period, and (2) anticonvulsants, which accounted for about a quarter of the volume and also had generic alternatives available during the same period.

Our price index for the individual NDCs of antidepressant and anticonvulsant drugs fell by nearly 10 percent and 15 percent, respectively, during the six-year period (data not shown). Growth in the prices for immunosuppressants has slowed in recent years due to generic entries in 2009. Other classes are made up almost entirely of brand-name drugs, and the prices of these products grew rapidly, ranging from increases of over 30 percent for antiretrovirals to increases of nearly 80 percent for antineoplastics.

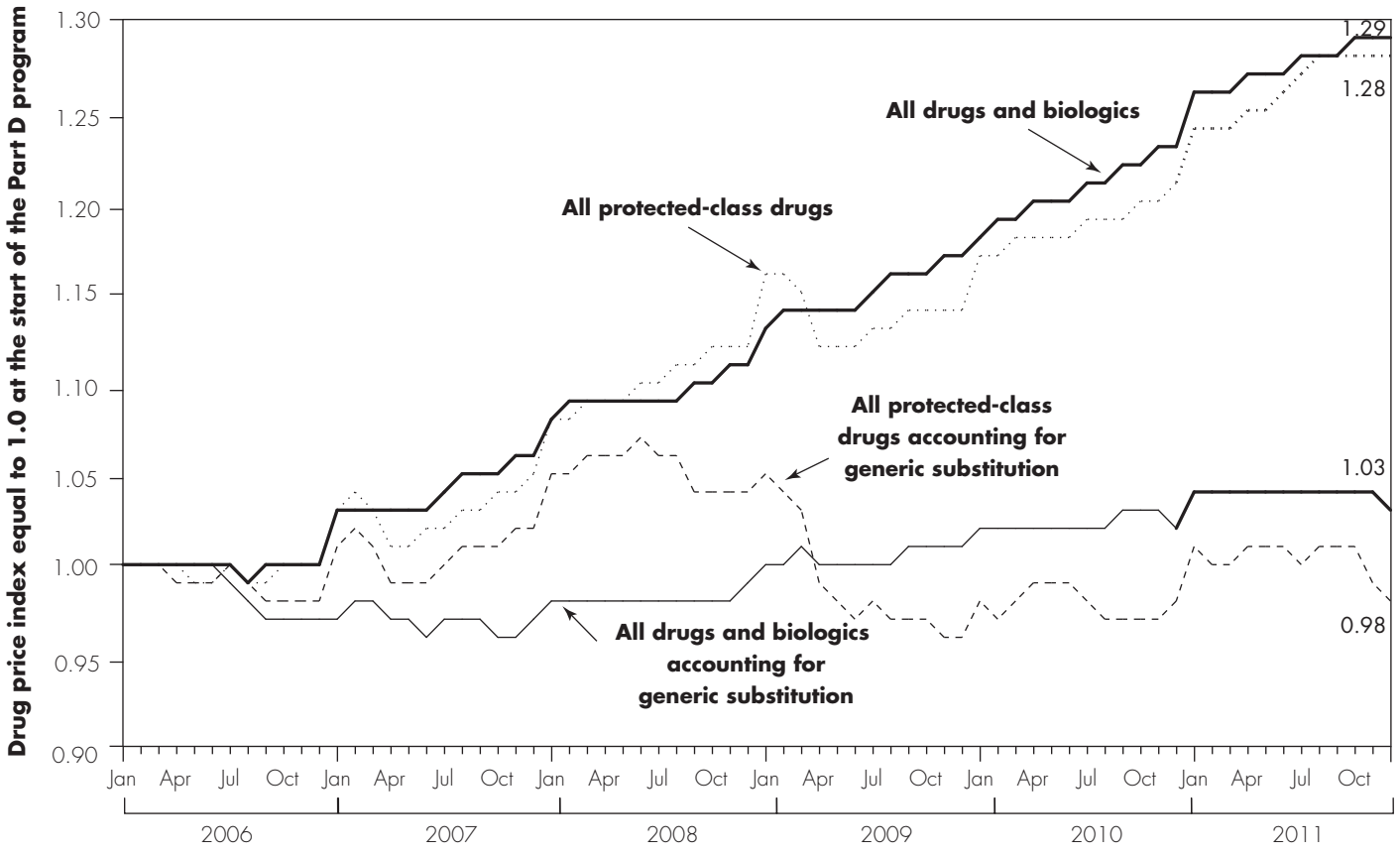
When protected-class drugs were grouped to take generic substitution into account, their prices fell by a cumulative 2 percent over the six-year period. Thus, despite the drugs' protected status, plan sponsors appeared to have had success at moving enrollees toward generics for these drugs when generic substitutes were available. However, the drugs' protected status may limit the amount of rebates plan sponsors are able to obtain from manufacturers for drugs in these classes. We lack rebate information to test this hypothesis.

Prices of brand-name drugs have grown aggressively

The patterns of price growth across different classes of drugs suggest that prices for drugs with few or no generic substitutes have grown rapidly. As expected, when we measured the price growth for drugs with no generic substitutes (single-source brand-name drugs) separately,

FIGURE 14–5

Availability of generics, rather than protected status, was key to slower price growth under Part D, 2006–2011



Note: The price index is a chain-weighted Fisher price index.

Source: Acumen, LLC analysis for MedPAC.

the growth in prices between 2006 and 2011 was much higher—an average of 66 percent cumulatively (Figure 14-6, p. 384). Prices of generic drugs, on the other hand, decreased to about 40 percent of the average prices observed at the beginning of 2006.

National average bid

Under Part D, payments to plans are based on the average of the bids that plan sponsors submit to CMS each year. The bids are intended to reflect the expected costs for a Medicare beneficiary of average health; CMS adjusts payments to plans based on the actual health status of each of the plan's enrollees. Growth in expected per capita benefit costs for Part D has fluctuated, ranging from nearly 9 percent between 2008 and 2009 to –4 percent between 2011 and 2012. For 2014, the expected costs were projected to increase by 4 percent (Table 14-15, p. 385). The actual costs of the program may be higher or lower than the prospective payments CMS makes to plans based on the bids.

Plan sponsors expecting lower cost for basic benefits but a much higher cost for reinsurance in 2014

Between 2013 and 2014, national average benefit costs for basic Part D benefits are projected to decrease by nearly 5 percent (Table 14-15, p. 385). During this period, the monthly payment to sponsors (i.e., the direct subsidy component) is projected to decrease by over 10 percent, while the reinsurance component is expected to grow by 20 percent. We have observed a similar trend for the last several years; the expected cost of providing the portion

Generic drug use has increased but varies across enrollees

The use of generic medications has increased over time. According to the Commission's analysis of the years 2007 to 2011, the overall average generic dispensing rate (GDR) increased from 61 percent to 77 percent (Table 14-14). During this period, some of the most popular brand-name drugs lost patent protection, affording more opportunities for generic substitution. GDRs vary across groups of beneficiaries. For example, Medicare Advantage–Prescription Drug (MA–PD) enrollees are more likely to use generic drugs than enrollees in prescription drug plans (PDPs). Between 2007 and 2011, MA–PDs consistently exceeded the GDR for PDPs by about 5 percentage points. Low-income subsidy (LIS) enrollees have had a consistently lower GDR than non-LIS enrollees, and that difference grew between 2007 and 2011 from 2 percentage points to 5 percentage points.

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. Also, there can be differences in the prescribing behavior of physicians who are part of a managed care organization and those who are not. Some of the difference in GDRs between PDPs and MA–PDs reflects the fact that most LIS enrollees are in PDPs. Since LIS enrollees are more likely to be disabled and tend to have a greater disease burden than non-LIS enrollees, they may have different medication needs. At the same time, because the LIS limits financial liability, some of the difference in the GDRs between LIS and non-LIS enrollees may be due to the difference in the financial incentives they face.

Over 80 percent of beneficiaries with high drug spending receive Part D's LIS, which pays for cost-sharing amounts above the statutorily set copayment. This subsidy may limit how well plan sponsors can manage drug spending for those individuals—for example, by limiting plans' ability to use reduced cost sharing to encourage the use of generic drugs when available. In our March 2012 report, we recommended that the Congress give the Secretary the authority to provide stronger financial incentives to use lower cost generics when they are available (Medicare Payment Advisory Commission 2012). ■

TABLE 14–14 **Generic dispensing rate by plan type and LIS status, 2007–2011**

	2007	2008	2009	2010	2011
All Part D	61%	67%	70%	74%	77%
By plan type					
PDP	60	66	69	72	75
MA–PD	66	71	74	77	80
By LIS status					
LIS	60	65	68	71	74
Non-LIS	62	69	72	76	79

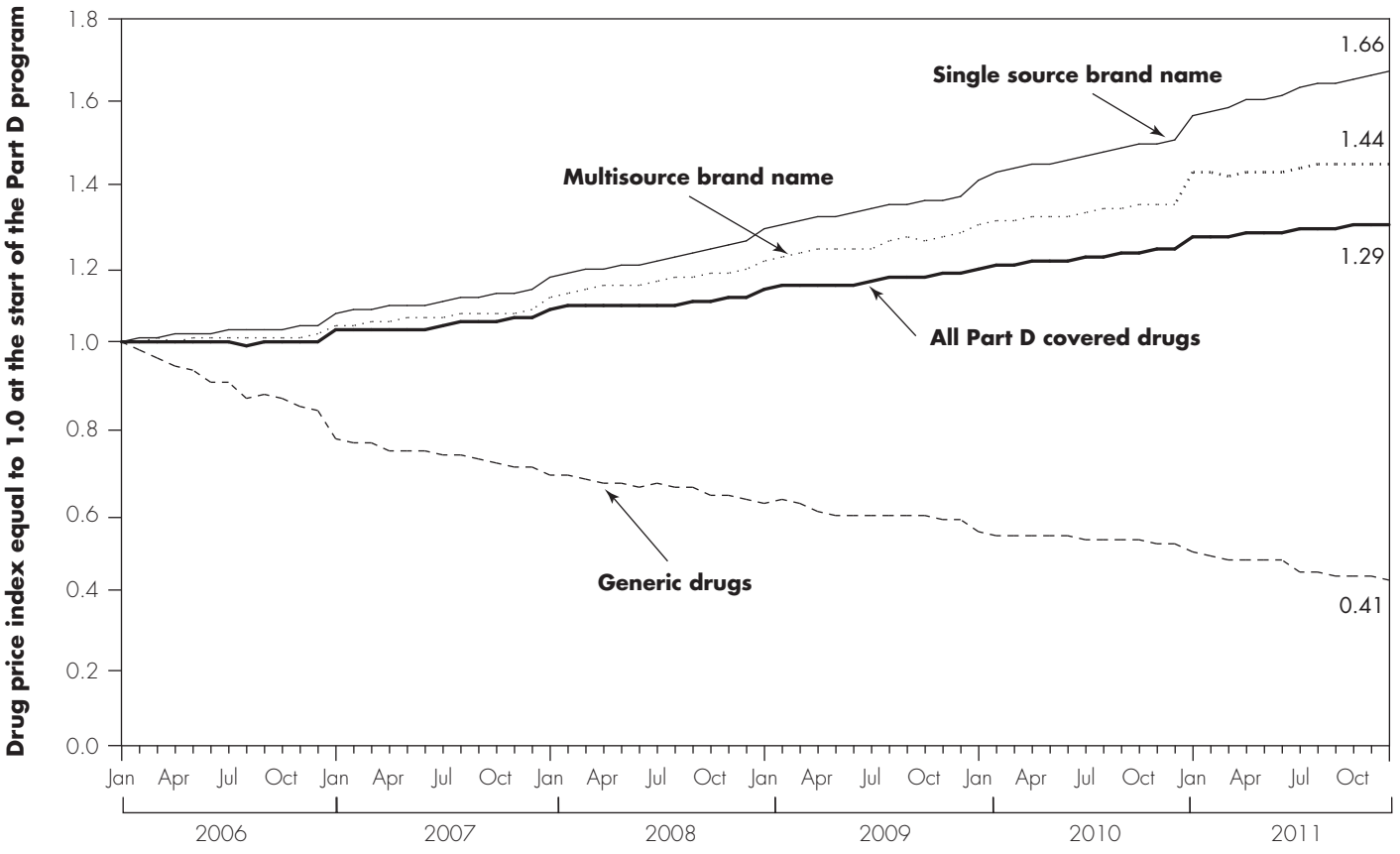
Note: LIS (low-income subsidy), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Shares are calculated as a percent of all prescriptions standardized to a 30-day supply. "Generic dispensing rate" is defined as the proportion of generic prescriptions dispensed. Part D drug event records are classified as PDP or MA–PD records based on the contract identification on each record.

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

of the benefit for which sponsors bear the most insurance risk has been decreasing, while the payments for which sponsors bear little or no insurance risk has been growing rapidly (see text box on changing priorities for sharing risk, p. 362).

The higher growth in the reinsurance component of the bid in most years since 2011 may, in part, be due to PPACA's gradual phase-out of the coverage gap. Part D reconciliation data through 2012 shows a larger net payment from Medicare to plans for the individual

FIGURE 14–6 **Sustained aggressive price growth under Part D for single-source brand-name drugs**



Note: The price index is a chain-weighted Fisher price index. Drug price index is equal to 1.0 at the start of Part D.

Source: Acumen, LLC analysis for MedPAC.

reinsurance in 2011 and 2012, suggesting plans underestimated the amount of spending in the catastrophic phase of the benefit.

In 2014, the base beneficiary premium is $32.42, an increase of 4 percent from $31.17 in 2013 (Table 14-15). The actual average monthly premium in 2014 differs from the base beneficiary premium since it depends on the beneficiary's plan choice. The base beneficiary premium reflects the basic portion of the benefit (the portion that does not include premiums for enhanced, or supplemental, benefits). The actual premium paid by individual beneficiaries is higher or lower depending on their selected plan's bid, their income level, and whether they are subjected to Part D's late enrollment penalty.

Quality in Part D

CMS collects quality and performance data for Part D plans to monitor sponsors' operations and help beneficiaries choose among plans. Plan ratings are displayed at www.medicare.gov, with the lowest rated plans flagged to caution beneficiaries about choosing those plans. The highest rated plans can enroll beneficiaries outside the annual open enrollment period. In addition, for MA–PDs, Part D performance data affect the overall plan ratings used by the MA program to determine the amount of bonus payments.

CMS relies on several sources for these data—the Consumer Assessment of Healthcare Providers and Systems survey, agency monitoring of plans, data provided

TABLE 14–15

National average bid and components of average prospective monthly payments per enrollee for basic coverage, 2009–2014

	2009	2010	2011	2012	2013	2014
Amount in dollars						
National average monthly bid						
Base beneficiary premium	$30.36	$31.94	$32.34	$31.08	$31.17	$32.42
Monthly payment to sponsors	53.97	56.39	54.71	53.42	48.47	43.46
Subtotal	84.33	88.33	87.05	84.50	79.64	75.88
Expected individual reinsurance	34.73	36.92	39.77	37.38	42.60	51.26
Total average benefit cost	119.06	125.25	126.82	121.88	122.24	127.14
Annual percent change						
National average monthly bid						
Base beneficiary premium	8.7%	5.2%	1.3%	–3.9%	0.3%	4.0%
Monthly payment to sponsors	2.6	4.5	–3.0	–2.4	–9.3	–10.3
Subtotal	4.7	4.7	–1.4	–2.9	–5.8	–4.7
Expected individual reinsurance	19.7	6.3	7.7	–6.0	13.9	20.3
Total average benefit cost	8.7	5.2	1.3	–3.9	0.3	4.0

Note: These amounts reflect averages based on bids to provide basic Part D benefits; they do not net out subsequent reconciliation amounts with CMS. They were calculated from bids by plans to provide the defined standard benefit or actuarially equivalent basic benefits, as well as the portion of enhanced Part D coverage attributable to basic benefits. Enrollees in plans with enhanced coverage must pay the full price of benefits that supplement basic coverage. The combination of monthly payments to plans and expected payments for individual reinsurance makes up 74.5 percent of total average monthly benefit costs. Bids are fully weighted by prior year enrollment.

Source: MedPAC based on CMS releases of Part D national average monthly bid amounts and base beneficiary premiums for 2009 through 2014, as well as other data provided by CMS.

by sponsors, and claims information (Centers for Medicare & Medicaid Services 2013c). For 2014, up to 15 metrics are grouped into four domains (Centers for Medicare & Medicaid Services 2013a):

- drug-plan customer service (three measures);
- member complaints, problems getting services, and improvement in the drug plan's performance (four measures);
- member experience with the drug plan (two measures); and
- patient safety and accuracy of drug pricing (six measures).

The star ratings on Medicare's web-based Plan Finder for MA–PDs are based on up to 48 measures, including measures that assess the quality of medical services provided under Part C (i.e., the MA program), in addition to the measures used to assess the quality of prescription drug (Part D) services provided. Since 2012, CMS has put more emphasis on intermediate outcome measures—such as the use of medications with a high risk of serious side effects and the share of enrollees obtaining medications recommended to treat selected conditions—and less emphasis on process measures, such as price accuracy on Medicare's Plan Finder. CMS aggregates individual scores for each measure (15 for PDPs and 48 for MA–PDs) on the Plan Finder under a 5-star system; 5 stars mean excellent performance, and 1 star reflects poor performance. CMS presents star ratings that combine individual scores in each domain as well as a summary rating that represents overall performance.

For 2014, ratings for both stand-alone PDP and MA–PD sponsors range from 2 stars to 5 stars. Weighted by enrollment, the average star rating among PDP sponsors is

3.04, compared with 3.3 for 2013, and the average among MA–PD sponsors is 3.84, compared with 3.66 for 2013 (Centers for Medicare & Medicaid Services 2013a). Much of the reduction in the average star rating among PDPs is attributable to contracts that are under CMS enrollment sanctions.[30] Ratings for contracts (only stand-alone PDPs) that are eligible to receive LIS autoassignments range from 2 stars to 4 stars, with no 5-star plans available. Compared with last year, fewer LIS plans have ratings below 3 stars, indicating potential improvement in quality.

Although star ratings for PDPs and MA–PDs are not directly comparable because the ratings are determined relative to other plans within the same plan type (PDP or MA–PD), the numeric averages that underlie individual measures allow for direct comparison of plan performances for each measure. For example, MA–PD sponsors were more likely to process appeals in a timely manner, and an external review entity was more likely to agree with coverage decisions made by MA–PDs compared with PDPs. MA–PDs were also less likely to use high-risk medications and more likely to follow recommended medication therapy for treating diabetes. PDPs, on the other hand, had fewer complaints from their enrollees and had higher adherence, on average, to medications to treat diabetes, hypertension, and high cholesterol. On other measures, such as members choosing to leave the plan and getting needed medications, the performances were about the same for both PDPs and MA–PDs.

Despite the shift in emphasis from process measures to outcome measures in rating plan quality and performance, we continue to be concerned about the quality of pharmaceutical care received by beneficiaries with multiple medications. They may have medical problems caused or exacerbated by their heavy use of medications (polypharmacy), and they are at increased risk of adverse drug events, drug-drug interactions, and use of inappropriate medications. As mentioned earlier, the current risk-sharing arrangement may limit how aggressively or successfully plan sponsors manage drug utilization for beneficiaries who take many medications (see text box on changing priorities for sharing risk, p. 362).

Part D plans are required to implement medication therapy management programs (MTMPs) to improve the quality of the pharmaceutical care that high-risk beneficiaries receive. However, our earlier review of the MTMPs revealed wide variations in eligibility criteria and the kinds of interventions provided to enrollees (Medicare Payment Advisory Commission 2009). In a recent evaluation, CMS found low enrollment in the program, with only a minority of enrollees receiving comprehensive medication reviews. Nevertheless, the report found some improvement in medication adherence for those participating in the program (Marrufo et al. 2013). Although the program has the potential to increase the quality of pharmaceutical care provided under Part D, we currently do not have sufficient data to determine how well it is working. We will continue to monitor this program and revisit this issue in the future. ■

Endnotes

1 PPACA eliminates the coverage gap by (1) requiring pharmaceutical manufacturers to offer a 50 percent discount on brand-name drugs filled during the coverage gap, (2) gradually phasing down cost sharing for generics and brand-name drugs, and (3) reducing the OOP threshold on OOP spending over the 2014 to 2019 period.

2 In 2014, the Part D benefit provides coverage of 2.5 percent for brand-name drugs, in addition to the 50 percent discount provided by pharmaceutical manufacturers, reducing the cost sharing for drugs filled during the coverage gap to about 47.5 percent. The cost-sharing amount for brand-name drugs filled during the coverage gap depends on the amount of the dispensing fee charged by a plan since the 2.5 percent covered by the Part D benefit applies to both the ingredient cost and the dispensing fee, while the 50 percent manufacturer discount applies only to the ingredient cost.

3 The amount of total covered drug spending at which a beneficiary meets the annual OOP threshold depends on the existence of other sources of supplemental coverage and the mix of brand-name and generic prescriptions an individual fills during the coverage gap. In 2014, the amount of total drug expenses at the annual OOP threshold of $6,690.77 is for an individual not receiving Part D's low-income subsidy and without other sources of supplemental coverage, assuming that expenses for brand-name drugs account for 86.2 percent of drug spending in the coverage gap. In 2012, 86.2 percent of spending below the OOP threshold by enrollees who did not receive low-income subsidies was for brand-name drugs.

4 Based on CMS's estimate as of October 2013.

5 Phone conversation with MAXIMUS on August 20, 2013.

6 The prescription drug coverage beneficiaries had before 2006 may or may not have been as generous as the Part D benefit. Since implementation of Part D, 90 percent of beneficiaries have drug coverage that is at least as generous as Part D's basic benefit.

7 In 2014, maximum cost-sharing amounts for full-benefit dual-eligible beneficiaries with income at or below 100 percent of the federal poverty level are $1.20 for generic drugs and $3.60 for brand-name drugs. The amounts for other full-benefit dual-eligible beneficiaries are $2.55 for generic drugs and $6.35 for brand-name drugs. Institutionalized full-benefit dual-eligible beneficiaries do not pay any cost sharing.

8 If an employer agrees to provide primary drug coverage to its retirees with an average benefit value that is equal to or greater than Part D (called creditable coverage), Medicare provides the employer with a tax-free subsidy for 28 percent of each eligible individual's drug costs that fall within a specified range of spending. Under PPACA, employers still receive the RDS on a tax-free basis, but beginning in 2013, they can no longer deduct prescription drug expenses for which they receive the subsidy as a cost of doing business (but they can still deduct prescription drug expenses not covered by the subsidy).

9 The employer group waiver plans provide the standard Medicare Part D prescription drug coverage only to the Medicare-eligible retirees and covered Medicare-eligible dependents of the sponsoring employer.

10 Medicare allows plan sponsors to offer two types of plans that have the same average benefit value as the defined standard benefit. The first type, which CMS calls actuarially equivalent, uses the same deductible as the defined standard benefit but has different cost sharing during the plan's initial coverage phase. The second type, called basic alternative, allows insurers to use a lower deductible than the defined standard benefit, different cost sharing, and a modified initial coverage limit. Because they have the same average benefit value as the defined standard benefit, in this chapter, we refer to both types as actuarially equivalent benefits.

11 Enhanced benefit plans that include coverage for drugs filled during the gap must provide such coverage beyond what is required by PPACA.

12 Under the Part C payment system, which is used to pay MA plans, a portion (between 58 percent and 71 percent in 2013) of the difference between the plan's benchmark payment and its bid for providing Part A and Part B services is referred to as Part C rebate dollars. The rebate dollars can be used to supplement benefits or lower premiums for services provided under Part C or Part D.

13 *Prior authorization* refers to requirements for preapproval from a plan before coverage. *Quantity limits* refer to a plan limiting the number of doses of a particular drug covered in a given time period. Under step therapy, plans require the enrollee to try specified drugs before moving to other drugs.

14 The amount in controversy (AIC) must be greater than the specified dollar thresholds. For 2014, the AIC thresholds are $140 and $1,430 for ALJ and federal district court, respectively (Centers for Medicare & Medicaid Services 2013d).

15 At least 90 percent of urban beneficiaries must live within 2 miles of an in-network pharmacy; at least 90 percent of

suburban beneficiaries must live within 5 miles, and at least 70 percent of rural beneficiaries must live within 15 miles.

16 For this analysis, we considered plans as having a preferred network only if the network included both preferred and nonpreferred pharmacies and there was differential cost sharing for the two types. Some plans report having preferred pharmacies in their network, but either they consider all in-network pharmacies as preferred or they have no cost-sharing differential between preferred and nonpreferred pharmacies. Those plans were excluded from this analysis because they did not meet both tests of a preferred network.

17 In a proposed rule published on January 6, 2014, CMS proposes to revise the definition of negotiated prices to require all price concessions from pharmacies to be reflected in negotiated prices. This policy is intended to standardize the reporting of costs and to ensure that plans are in compliance with CMS's regulation requiring that any reduction in cost sharing not increase CMS payments to plans.

18 Preferred and nonpreferred cost-sharing differentials are based on cost-sharing amounts for Region 12 (Alabama–Tennessee region) when available. Some plan offerings have slight differences in cost sharing from region to region. All plans have a specialty tier but none varied cost sharing on the specialty tier.

19 CMS allows a sponsor to offer multiple plans in any given service area only if those offerings are substantially different from one another. In order to be considered "substantially different," for 2014 plans must have a difference of at least $21 per month in a beneficiary's expected monthly OOP costs between basic and enhanced plans. If a sponsor is offering two enhanced plans in the same service area, in 2014 the second enhanced plan must have a higher value than the first, with a difference of at least $18 in a beneficiary's expected monthly OOP costs between the two enhanced plan offerings.

20 The number of LIS benchmark plans (352 PDPs) includes 27 SmartD Rx plans and 31 Silverscript plans that are under CMS sanctions and are therefore not eligible to receive LIS reassignments.

21 E-mail communication with CMS staff, December 4, 2013.

22 The actual cost-sharing amount for brand-name drugs will depend on the amount of the dispensing fee charged by a plan since the 2.5 percent covered by the Part D benefit applies to both the ingredient cost and the dispensing fee, while the 50 percent manufacturer discount applies only to the ingredient cost.

23 The number of drugs in the formulary reference file, which is used as a denominator to calculate the share of all distinct chemical entities listed on plan formularies, increased by about 5 percent between 2013 and 2014.

24 The share of all formulary generic drugs on nonpreferred tiers among PDPs that use a nonpreferred-generic tier is higher (over 80 percent) when weighted by enrollment.

25 Lower subsidy rates apply to higher income beneficiaries. For more information, refer to the section on premiums.

26 Many high-priced medications are biologics—that is, drug products derived from living organisms. They are often used to treat diseases like cancer, anemia, chronic kidney disease, rheumatoid arthritis, and multiple sclerosis. These products generally have high launch prices, and the lack of competition has made it difficult for both public and private payers to negotiate lower prices with manufacturers.

27 An individual NDC uniquely identifies the drug's labeler, drug, dosage form, strength, and package size. Because each drug often is available in different dosages, strengths, and package sizes, the same drug typically has many different NDCs.

28 For this index, Acumen groups NDCs that are pharmaceutically identical, aggregating prices across drug trade names, manufacturers, and package sizes. As a result, brand-name drugs are grouped with their generics if they exist, and the median price more closely reflects the degree to which market share has moved between the two.

29 In a proposed rule published on January 6, 2014, CMS proposes to remove three classes—antidepressants, antipsychotics, and immunosuppressants for transplant rejection—from the protected status.

30 As of December 2013, two plans, the SmartD Rx PDPs and the SilverScript PDPs, with a combined enrollment of nearly 3.5 million in 2013, are under CMS sanctions and are banned from accepting new enrollees.

References

Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. 2013. *2013 annual report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds.* Washington, DC: Boards of Trustees.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013a. *2014 Part C and D plan ratings.* Fact sheet. Baltimore, MD: CMS.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013b. Best practices and common findings memo #2 from 2012 program audits. Memo to all Medicare Advantage organizations and prescription drug plans from Gerard Mulcahy, Director, Medicare Parts C and D Oversight and Enforcement Group. July 30.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013c. *Medicare health & drug plan quality and performance ratings 2013 Part C & Part D technical notes.* Updated September 27. Baltimore, MD: CMS.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013d. Medicare program; Medicare appeals: Adjustment to the amount in controversy threshold amounts for calendar year 2014 Notice. *Federal Register* 78, no. 188 (September 27): 59702–59704.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013e. *Part D claims analysis: Negotiated pricing between preferred and non-preferred pharmacy networks.* April 30. Baltimore, MD: CMS. http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/PharmacyNetwork.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2013f. *The 2012 Part C and Part D program audit annual report.* Report issued by the Medicare Parts C & D Oversight and Enforcement Group Baltimore, MD: CMS. http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2012-Part-C-Part-D-Program-Audit-Annual-Report-.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2011a. *Code of Federal Regulations.* 423.120(a)(9). Access to covered Part D drugs. http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol3/pdf/CFR-2011-title42-vol3-sec423-120.pdf.

Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2011b. *Prescription Drug Benefit Manual. Chapter 5: Benefits and beneficiary protections.* Baltimore, MD: CMS. http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

Congressional Budget Office. 2010. *Effects of using generic drugs on Medicare's prescription drug spending.* Washington, DC: CBO.

Department of Health and Human Services. 2010. Prescription drug cost relief to more than 750,000 Medicare beneficiaries. News release. August 10. http://www.hhs.gov/news/press/2010pres/08/20100810a.html.

Hargrave, E., L. Summer, D. Liffmann, et al. 2012. *Findings from focus groups with beneficiaries and physicians and site visits with physicians, care coordinators, and other staff.* Report prepared by staff from NORC at the University of Chicago for MedPAC. Washington, DC: MedPAC.

Hoadley, J., J. Cubanski, E. Hargrave, et al. 2013a. *Medicare Part D: A first look at plan offerings in 2014.* Issue brief. Menlo Park, CA: Kaiser Family Foundation.

Hoadley, J., L. Summer, E. Hargrave, et al. 2013b. Plan switching by Medicare Part D enrollees. Presentation by staff from Georgetown Health Policy Institute and NORC at the University of Chicago.

Hoadley, J. F., K. Merrell, E. Hargrave, et al. 2012. In Medicare Part D plans, low or zero copays and other features to encourage the use of generic statins work, could save billions. *Health Affairs* 31, no. 10 (October): 2266–2275.

Keenan, T. A. 2007. *Prescription drugs and Medicare Part D: A report on access, satisfaction, and cost.* Washington, DC: AARP.

Marrufo, G., A. Dixit, D. Perlroth, et al. 2013. *Medication therapy management in a chronically ill population: Interim report.* Prepared for the Centers for Medicare & Medicaid Services by Acumen, LLC. Contract # HHSM–500–2011–00012I/TOT0001. Baltimore, MD: CMS.

Medical News Today. 2009. Medicare Part D continues to earn strong marks from America's seniors. http://www.medicalnewstoday.com/releases/170820.php.

Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2012. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2009. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

Medicare Payment Advisory Commission. 2008. *Report to the Congress: Medicare payment policy.* Washington, DC: MedPAC.

NORC at the University of Chicago. 2013. Memo from NORC staff to MedPAC staff regarding network and preferred pharmacies in 2013 Part D plans. November.

Office of Inspector General, Department of Health and Human Services. 2007. *Generic drug utilization in the Medicare Part D program.* No. OEI–05–07–00130. Washington, DC: OIG.

PRNewswire. 2010. Medicare Part D continues to earn strong marks from America's seniors. http://www.prnewswire.com/news-releases/medicare-part-d-continues-to-earn-strong-marks-from-americas-seniors-69867642.html.

Schmidt, R. 2011. Options for sharing risk in Medicare Part D. A report submitted to the Medicare Payment Advisory Commission.

Suzuki, S. 2013. "Do Part D enrollees switch plans?: Prevalence and potential factors affecting their decisions." Unpublished manuscript submitted to *Medical Care Research and Review* on August 28, 2013. Manuscript ID number MCRR–2013–0120–DT.

Weems, K. 2008. The Medicare drug benefit: Are private insurers getting good discounts for the taxpayer? Statement by Kerry Weems, Acting Administrator, Centers for Medicare & Medicaid Services, before the Committee on Oversight and Government Reform, House of Representatives. 110th Congress, 2nd sess. July 24.