pharmacies from their commercial networks that they believe have especially close ties to drug manufacturers. Smaller independent specialty pharmacies counter that PBMs are trying to divert those prescriptions to their own larger specialty pharmacies (Staton 2015, Thomas 2017).

More representative of the industry are specialty pharmacies that dispense drugs from a variety of manufacturers. However, financial incentives can differ across companies. Some pharmacies may earn relatively more revenue from drug manufacturers (e.g., for monitoring patient adherence or collecting REMS data) and may have weaker incentives to negotiate for lower drug prices. Other firms have incentives more closely tied to payers and PBMs.

As with general retail pharmacies, Part D plan sponsors negotiate agreements with specialty pharmacies that include DIR fees that are typically collected after the prescription has been filled. The growing dollar amounts of those fees, their retrospective nature, and the criteria plan sponsors use for setting performance-based fees have led to strong criticism from independent specialty pharmacies (Blank 2016, Seeking Alpha 2016).[36]

Drug pricing

The end of the patent cliff (the period around 2012 when sales of brand-name medicines fell dramatically as the drugs lost patent protection) and the diminishing opportunity for new generic savings has coincided with a pipeline shift toward higher cost medications, resulting in aggressive growth in prices. In recent years, a number of biopharmaceutical manufacturers have transformed their research and development strategies toward markets for orphan drugs (special status given to drugs under development to treat rare diseases or conditions) and targeted therapies (EvaluatePharma 2016). The Food and Drug Administration's (FDA's) approvals of innovative medicines in the last few years have included an increasing number of biologics and specialty drugs, with new medicines focused on treatments for a range of cancers, hepatitis C, autoimmune diseases, and heart disease, among others.[37] Many of these new entrants command higher prices than existing therapies and generally have few or no lower cost alternatives. This trend is likely behind the recent growth in spending accounted for by biologics and specialty-tier drugs. Between 2011 and 2014, Part D spending on biologics grew by 31 percent per year, on average. During the same period, specialty-tier drugs, some of which are biologics, grew by 37 percent per year, on average.[38]

Another factor that is likely contributing to the growth in prices is the increasing use of price-protection rebates that may exacerbate the inflationary trend (see section on manufacturer rebates, pp. 401–403). While the arrangement allows more predictability in benefit costs for plan sponsors, that protection could allow manufacturers to increase their prices with less resistance from plan sponsors.

Changes in the market dynamics of the supply and distribution channels are putting upward pressure on prices and rebates, driving the growing divergence between gross (or list) prices and net prices (prices net of rebates and discounts obtained from manufacturers and pharmacies). This phenomenon is not limited to the Part D program. According to the estimates from IMS Health's Institute for Healthcare Informatics, between 2014 and 2015, total spending based on invoice (list) prices grew by 12.2 percent compared with 8.5 percent growth in net prices (IMS Institute for Healthcare Informatics 2016).[39]

The cost of providing the Part D benefit is affected both by prices net of rebates and discounts and by gross (or list) prices paid at the pharmacies. While the former affects plan premiums, the latter affects patient cost sharing and the rate at which patients reach the catastrophic phase of the benefit, where Medicare pays 80 percent of the costs in individual reinsurance. Thus, gross prices paid at the pharmacies are also an important indicator of Part D's costs from beneficiaries' and Medicare's perspectives.

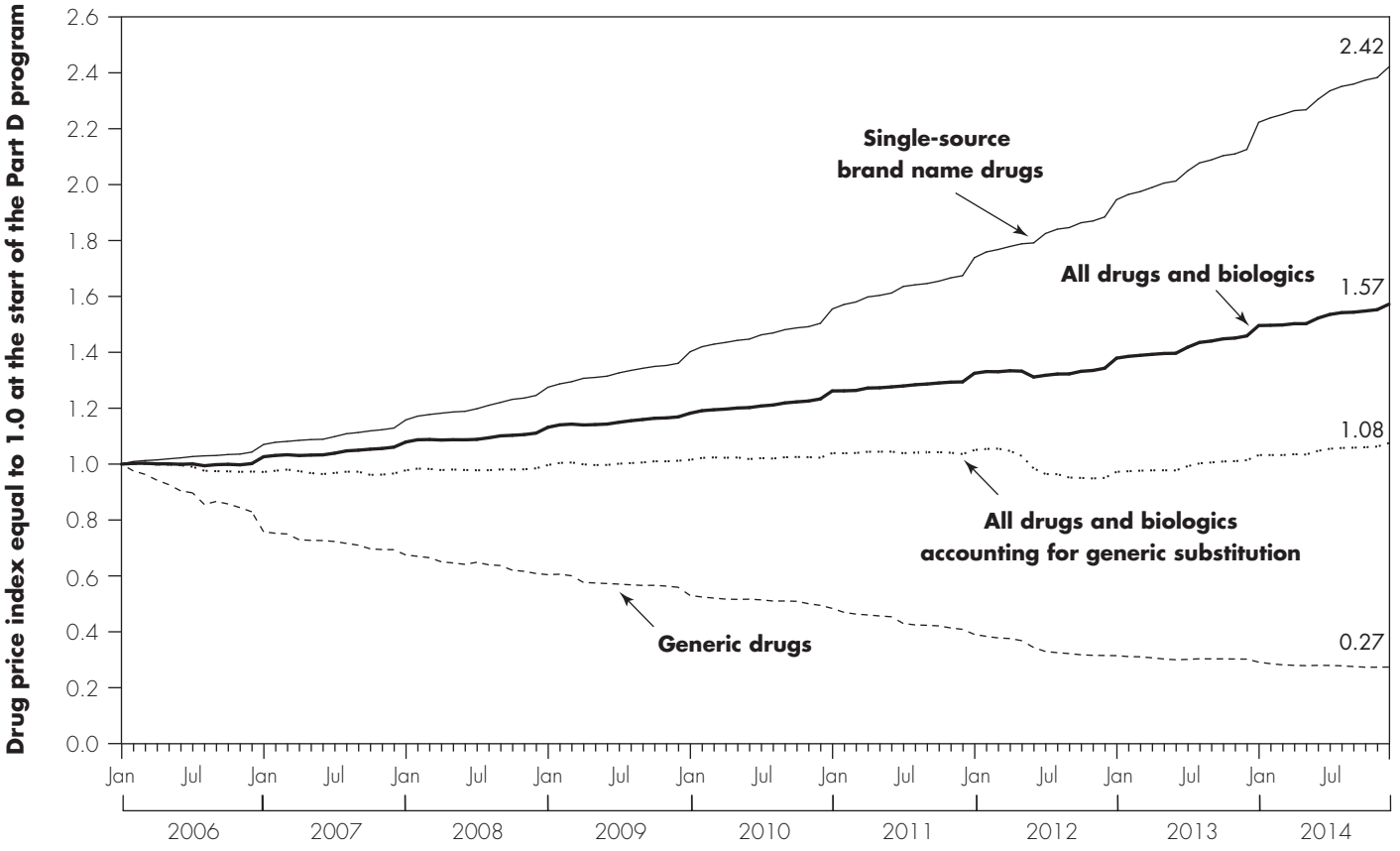
To track gross drug prices paid to pharmacies, the Commission has contracted with Acumen LLC for many years to construct a series of volume-weighted price indexes. The indexes do not reflect retrospective rebates or discounts from manufacturers and pharmacies; they reflect total amounts paid to the pharmacies, including ingredient costs and dispensing fees.

In 2014, price increases for brand-name drugs overwhelmed the effects of using lower priced generics

Measured by individual national drug codes (NDCs) and excluding manufacturers' rebates, between 2006 and 2014, Part D drug prices rose by an average of 57 percent cumulatively (an index value of 1.57) (Figure 14-5).[40] As measured by a price index that takes the substitution of

FIGURE 14–5

Price increases for brand-name drugs are overwhelming the effects of using lower priced generics



Note: Chain-weighted Fisher price indexes.

Source: Acumen LLC analysis for MedPAC.

generics for brand-name drugs into account, Part D prices increased by 8 percent cumulatively.[41] The uptick in this price index during 2013 and 2014 is a dramatic shift from prior years when increased generic use had offset the increases in prices of brand-name drugs to keep overall prices stable.

On average, generic drugs have prices that are 75 percent to 90 percent lower than the prices of brand-name drugs, and those prices tend to decline over time (Government Accountability Office 2016). However, in recent years, several analysts have noted that certain generic medications now have high prices or have experienced sharp price increases (Alpern et al. 2014, Fein 2014b, Kesselheim 2014). A number of factors explain price increases for generics, such as drug shortages, disruptions in the supply of drugs, and consolidations among manufacturers of generic drugs (Alpern et al. 2014). Factors associated with decreased market competition can lead to high and rising prices. Overall, the Commission's generic price index decreased at a slower rate between December 2012 and December 2014 (on average, about –7 percent annually) compared with double-digit declines in nearly every year between 2006 and 2012. Still, between 2006 and 2014, prices of generic drugs decreased to 27 percent of the average prices observed at the beginning of 2006 (Figure 14-5).

In comparison, prices of drugs with no generic substitutes (single-source, brand-name drugs) grew by a cumulative 142 percent during the same period. The price increases for brand-name drugs are overwhelming the effects of using lower priced generic drugs, even as the share of

Generic use has risen but varies across plan types and enrollees

Increased use of generics has played a major role in moderating Part D spending growth. Between 2007 and 2014, the average generic dispensing rate (GDR)—defined as the share of Part D prescriptions dispensed that are generic drugs—increased from 61 percent to 85 percent (Table 14-10). During this period, some of the most popular brand-name drugs lost patent protection, affording more opportunities for generic substitution.

GDRs vary across categories of beneficiaries. For example, Medicare Advantage–Prescription Drug plan (MA–PD) enrollees are more likely to use generics than prescription drug plan (PDP) enrollees. Between 2007 and 2014, the average GDR for MA–PD enrollees consistently exceeded those of PDP enrollees by 4 percentage points to 6 percentage points. The average GDR of low-income subsidy (LIS) enrollees has been consistently lower than that for non-LIS enrollees, and the difference has remained stable at about 4 percentage points to 5 percentage points since 2008.[42]

In both PDPs and MA–PDs, LIS enrollees are less likely than non-LIS enrollees to use generic drugs. For example, among PDP enrollees in 2014, the GDR for LIS enrollees was nearly 3 percentage points below that of non-LIS enrollees. Among MA–PD enrollees in the same year, the GDR for LIS enrollees was more than 5 percentage points lower (data not shown).

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. There can also be differences in prescribing behavior between physicians who are part of a managed care organization and those who are not. Another factor may be the difference in financial incentives faced by LIS and non-LIS enrollees. Because cost sharing for LIS enrollees is set statutorily, that factor may limit how well plan sponsors can manage drug spending for their LIS enrollees.

One of the Commission's June 2016 recommendations was intended to encourage LIS enrollees to use generics when they are available. Greater use of generics would likely reduce Medicare spending for the LIS. It could also reduce the amount Medicare pays in individual reinsurance since about three-fourths of enrollees who reach the catastrophic phase of the benefit receive the LIS. ■

TABLE 14–10 **Generic dispensing rate by plan type and LIS status, 2007–2014**

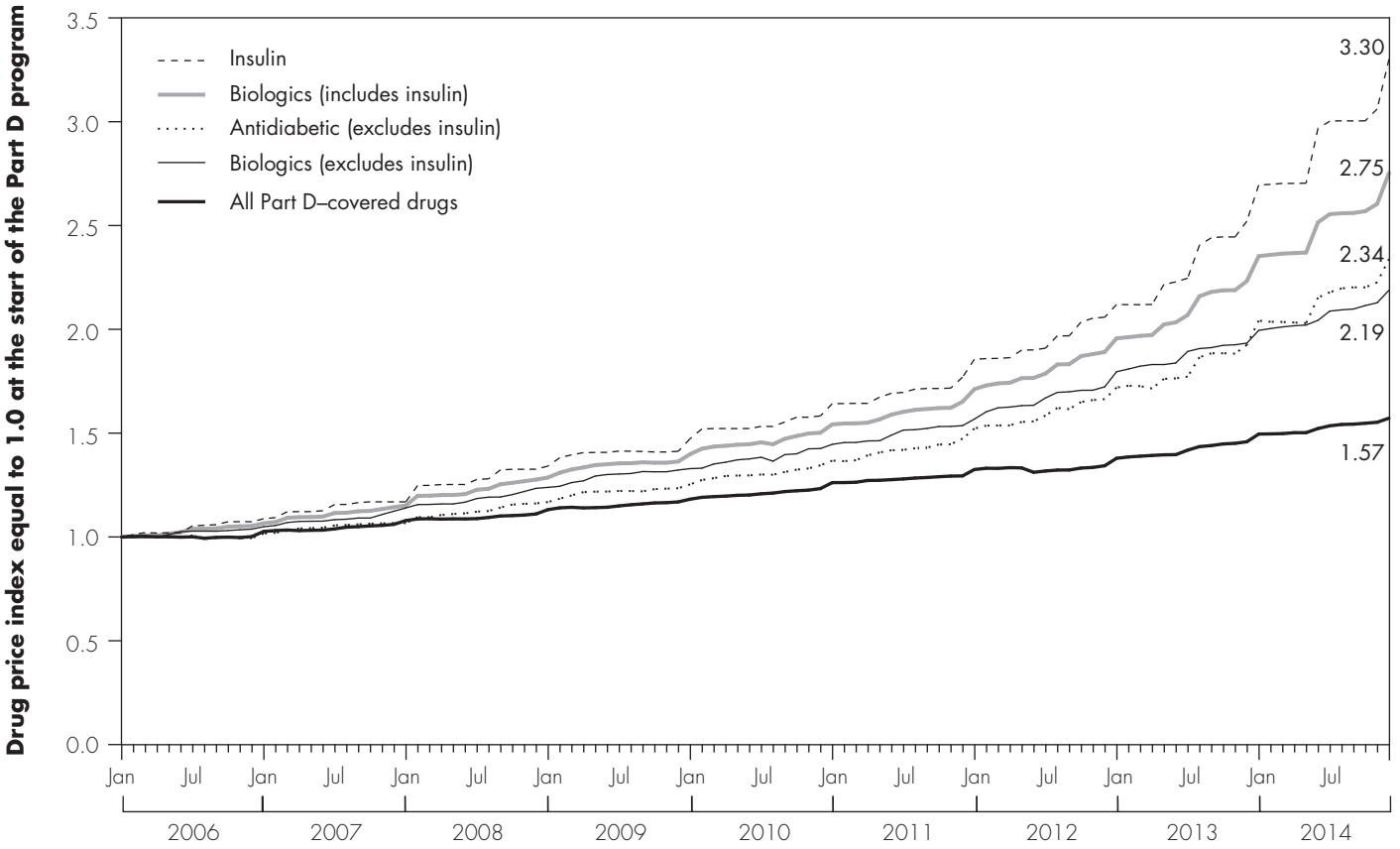
	2007	2008	2009	2010	2011	2012	2013	2014
All Part D	61%	67%	70%	74%	77%	81%	84%	85%
By plan type								
PDP	60	66	69	72	75	80	82	84
MA–PD	66	71	74	77	80	84	86	88
By LIS status								
LIS	60	65	68	71	74	78	81	83
Non-LIS	62	69	72	76	79	83	85	87

Note: LIS (low-income subsidy), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]). Shares are calculated as a percentage of all prescriptions standardized to a 30-day supply. "Generic dispensing rate" is the proportion of Part D prescriptions dispensed that are generic prescriptions.

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

FIGURE 14–6

Prices of biologics, including insulin products, have grown aggressively



Note: Chain-weighted Fisher price indexes.

Source: Acumen LLC analysis for MedPAC.

generic prescriptions continues to rise (see text box on generic use). In 2012, the Part D price index experienced its largest ever decline (8.2 percent) as a result of the so-called "patent cliff." Subsequent changes between 2012 and 2014 suggest a strong uptick in prices of medicines taken by enrollees that more than offset the moderating effects of switching to generic medications.

Prices of biologics and drugs in certain therapeutic classes have grown more aggressively

Patterns of price growth across classes of drugs suggest that prices for drugs with few or no lower cost generic or biosimilar alternative have grown rapidly. In the last few years, spending for biologics has increased more rapidly than overall (gross) drug spending in Part D. This spending growth has been driven by increases in the average price per biologic dispensed, which reflects both price inflation and the use of a more expensive mix of therapies. Among biologic products covered through Part D, few have follow-on products on the market that compete with them through price. Our price index for biologic products grew between 2006 and 2014 by a cumulative 175 percent (index value of 2.75)—much higher than the 57 percent growth across all drugs and biologics covered under Part D during the same period (Figure 14-6).

Biologics covered under Part D fall into two broad categories. The first group includes older molecules, such as insulin, human growth hormone, and other hormones. These products tend to have larger markets and lower prices than many of the newer biologics. The second

TABLE 14–11

Availability of generics, rather than protected status, is key to slower price growth under Part D

	Chain-weighted Fisher price index								
Protected classes	**January 2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
All six protected classes	1.00	1.05	1.12	1.14	1.21	1.27	1.30	1.40	1.44
Antidepressants	1.00	0.87	0.87	0.91	0.94	0.90	0.97	1.03	0.73
Antipsychotics	1.00	1.14	1.25	1.32	1.43	1.60	1.50	1.52	1.63
Anticonvulsants	1.00	1.00	1.06	0.87	0.83	0.80	0.81	0.94	1.03
Antineoplastics	1.00	1.14	1.24	1.37	1.53	1.67	1.81	2.00	2.21

Note: Two other drug classes are not shown but also have protected status: antiretrovirals and immunosuppressants for the treatment of transplant rejection. In 2014, 80 percent or more of prescriptions dispensed for antidepressants, antipsychotics, and anticonvulsants were generic.

Source: Acumen LLC analysis for MedPAC.

group includes newer, more complex biologics, such as monoclonal antibodies and other therapeutic proteins that tend to have more limited markets and high launch prices.

Insulin (used for the treatment of diabetes) is the largest therapeutic class of biologics in Part D. During the 2011 to 2014 period, prescriptions for insulin accounted for nearly 90 percent of all prescriptions for biologics, and the share of biologics spending accounted for by insulin grew from 55 percent to 59 percent (data not shown). Our price index for insulin (measured at individual NDCs) for that period more than tripled. This level of growth far exceeds the price index growth observed for other biologics (in December 2014, price index of 2.19 compared with 3.30 for insulin) and for other (noninsulin) antidiabetics (in December 2014, price index of 2.34) (Figure 14-6, p. 411).

In general, plan sponsors have had success at moving enrollees toward generics, which helps to slow the growth in prices, even when a drug has protected status. As measured by individual NDCs, prices for drugs in the six protected classes showed a moderate trend between 2006 and 2014, rising by a cumulative 44 percent (Table 14-11). When protected-class drugs were grouped to take generic substitution into account, their prices fell by a cumulative 13 percent over the nine-year period (data not shown).

These trends are influenced heavily by three classes of drugs: antidepressants, antipsychotics, and anticonvulsant medications, which accounted for over 90 percent of the volume of prescriptions in the six protected classes. In 2014, 80 percent or more of prescriptions dispensed for these three classes of drugs were generic. In the case of anticancer drugs, however, growth in prices for very expensive brand-name medications has driven overall growth in the category. Our price index for antineoplastics (measured at individual NDCs) between 2006 and 2014 grew by more than 120 percent.

While the drugs' protected status does not appear to affect plan sponsors' ability to encourage the use of generics, it 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.

Program costs

Costs of providing Part D benefits are shared by Medicare and the enrollees. Medicare pays plan sponsors three major subsidies on behalf of each of their enrollees:

- ***Direct subsidy***—Medicare pays plans a monthly prospective amount set as a share of the national average bid for Part D basic benefits, adjusted for the risk of the individual enrollee.
- ***Reinsurance***—Medicare reimburses plans for 80 percent of drug spending above an enrollee's annual OOP threshold. Plans receive prospective payments for reinsurance that are reconciled after the end of

TABLE 14–12

Medicare's reimbursement amounts for Part D

	2007	2009	2011	2012	2013	2014	2015	Average annual growth rate 2007–2015
Reimbursement amount (in billions):								
Direct subsidy*	$17.6	$18.2	$19.2	$19.7	$19.6	$18.5	$18.6	0.7%
Reinsurance	8.0	10.1	13.7	15.5	19.2	27.2	34.3	20.0
Low-income subsidy	16.7	19.6	22.2	22.5	23.2	24.3	25.8	5.6
Retiree drug subsidy	3.9	3.9	3.6	3.0	1.7	1.5	1.4	–12.0
Total	46.2	51.8	58.7	60.7	63.7	71.5	80.1	7.1
Enrollee premiums	4.1	6.1	7.3	7.8	9.3	10.5	11.5	13.8

Note: Numbers above reflect reconciliation. Components may not sum to stated totals due to rounding.
*Net of risk-sharing payments using Part D's risk corridors.

Source: MedPAC based on Table IV.B10 of the 2016 annual report of the Boards of Trustees of the Medicare trust funds.

the benefit year to reflect actual spending for each enrollee that reached the OOP threshold.

- ***LIS***—Medicare pays plans to cover cost sharing and premiums for enrollees eligible for the low-income subsidy.

Combined, the direct subsidy and expected reinsurance payments are designed to cover 74.5 percent of the expected cost of basic benefits.

Beneficiary premiums cover the remaining 25.5 percent of the expected cost of basic benefits. Part D enrollees also pay any cost sharing required by plan sponsors.

Higher effective subsidy rates increasing overall program costs

Evidence on program spending gives a mixed picture of the success of Part D plans at containing costs. In the Commission's June 2015 report to the Congress, we noted regular patterns in Medicare's reconciliation payments with plans (Medicare Payment Advisory Commission 2015a). First, many plan sponsors bid too low on the amount of benefit spending they expected above Part D's catastrophic threshold relative to their enrollees' actual catastrophic spending. Second, plan sponsors bid too high on the rest of benefit spending other than catastrophic benefits. Spending for the competitively derived direct-subsidy payments on which sponsors bear the most insurance risk has grown slowly, while benefit spending on which sponsors bear no insurance risk (low-income cost sharing) or limited risk (the catastrophic portion of the benefit, for which Medicare provides 80 percent reinsurance) has grown much faster (Medicare Payment Advisory Commission 2015a).

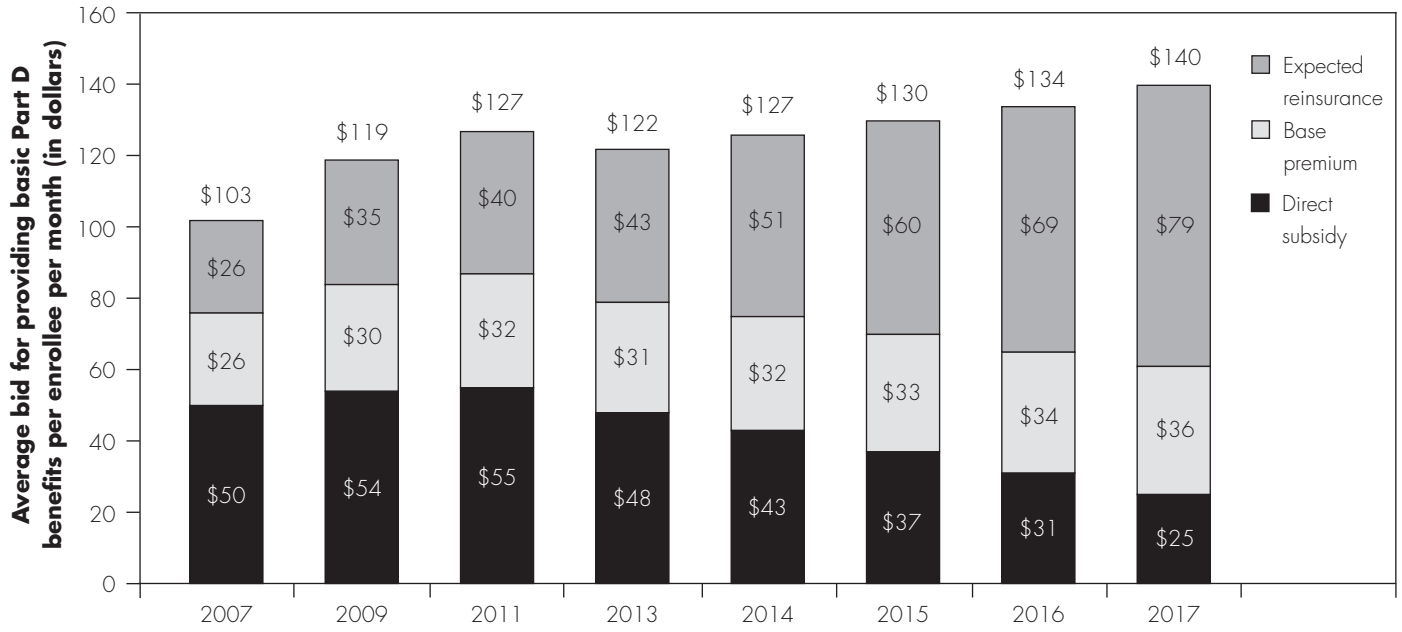
Between 2009 and 2015, the majority of parent organizations returned a portion of their prospective payments to Medicare through risk corridors.[43] Actuaries interviewed by Commission staff suggested that there is significant uncertainty behind the assumptions they make when projecting drug spending for their bids. At the same time, we suggested Part D's risk-sharing mechanisms may provide incentives to bid too low on catastrophic spending and too high on spending for the remainder of the Part D benefit. This dynamic and the open-ended nature of retrospective payments for reinsurance have resulted in effective Medicare subsidy rates for Part D that have been higher than 74.5 percent in most years.

Trends in program subsidies and costs

Between 2007 and 2015, program spending (including the retiree drug subsidy (RDS)) rose from $46.2 billion to $80.1 billion (Table 14-12). In 2015, Medicare paid $18.6 billion for direct subsidies, $34.3 billion for individual reinsurance, $25.8 billion for the LIS, and $1.4 billion for the RDS (Boards of Trustees 2016). Medicare's overall program spending grew by an average of 7.1 percent per year.

FIGURE 14–7

National average plan bid for basic Part D benefits



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

Source: MedPAC based on data from CMS.

In 2015, premiums paid by Part D enrollees (not including the premiums paid by Medicare on behalf of LIS enrollees) totaled $11.5 billion (Boards of Trustees 2016). This amount grew by an average 13.8 percent per year since 2007, reflecting both increases in benefit costs and growth in enrollment, particularly among beneficiaries who do not receive the LIS.

In addition to monthly premiums, most enrollees are responsible for paying cost sharing as set by plan sponsors or, in the case of LIS enrollees, an amount set in law. (On behalf of LIS enrollees, Part D's low-income cost-sharing subsidy pays for the difference between cost sharing set by plan sponsors and the nominal amounts they pay out of pocket.) In 2015, OOP spending by enrollees for cost sharing totaled $15.1 billion (Centers for Medicare & Medicaid Services 2016b).[44]

Continued rapid growth in spending for reinsurance

Medicare payments for individual reinsurance have grown faster than other components of Part D spending. Between 2007 and 2015, payments for individual reinsurance increased at an annual average of 20 percent and have been the largest component of Part D spending since 2014 (Table 14-12, p. 413). This growth appears to have accelerated in recent years, growing at an annual average of 25 percent between 2010 and 2015 compared with 12 percent for 2007 through 2010 (data not shown). This faster growth is due, in part, to the gradual phase-out of the coverage gap that began in 2011. Since 2010, there has been a double-digit increase in the number of non-LIS enrollees who reach the catastrophic phase of the benefit, which, in turn, triggers Medicare's individual reinsurance (see text box on beneficiaries who reach the coverage gap or out-of-pocket threshold (opposite page) and Table 14-13, p. 416).

Changes in the national average bid also reveal higher growth in individual reinsurance. Between 2007 and 2016, expected total benefit spending per member per month has grown at a modest rate of about 3 percent annually, from $103 to $140 (Figure 14-7). During that period, the monthly amount that plans expect to receive through the direct subsidy has fallen 6.6 percent annually, from about

Beneficiaries who reach the coverage gap or out-of-pocket threshold

In 2014, 10.6 million, or 28 percent, of Part D enrollees incurred spending high enough to reach the coverage gap, up from about a quarter in 2013 (Figure 14-8). Of those, 3.4 million, or almost 9 percent, of Part D enrollees had spending high enough to reach the catastrophic phase of the benefit, up from 2.9 million in 2013. We refer to individuals who reach the catastrophic phase as high-cost enrollees.

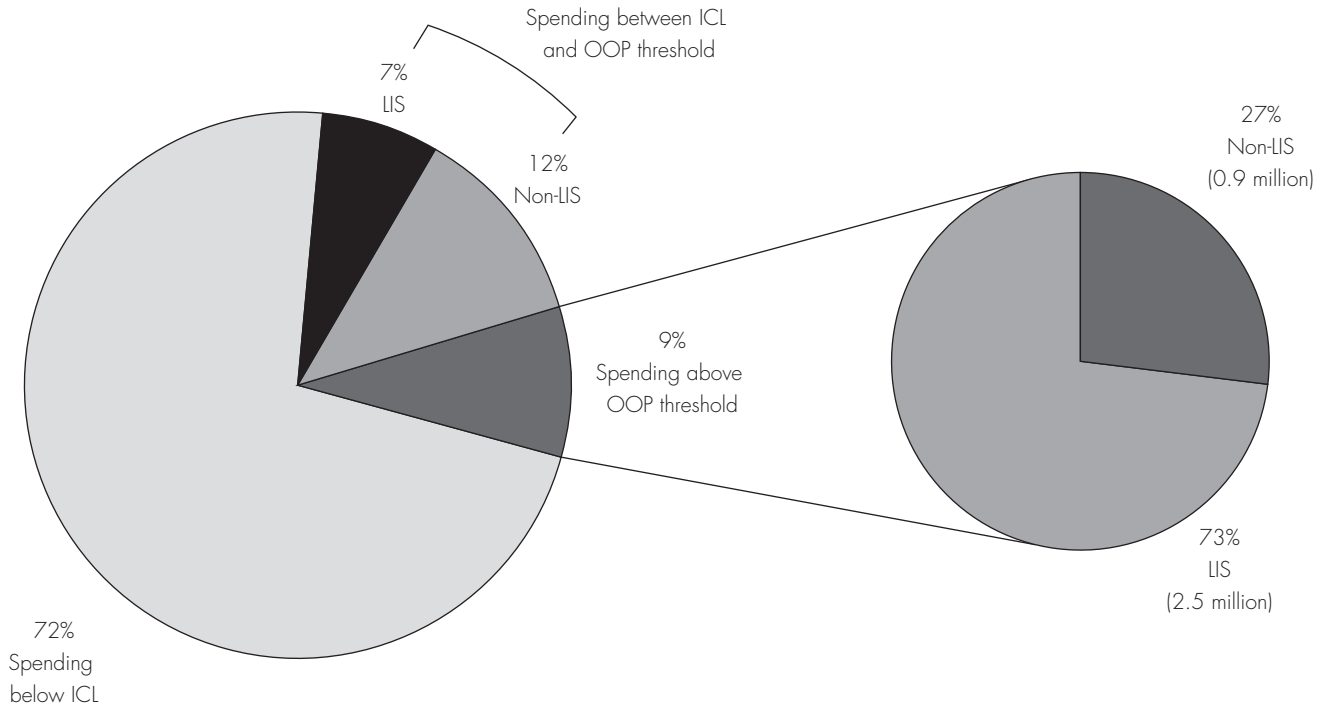
Most high-cost enrollees received the LIS, but number of non-LIS enrollees growing faster

In 2014, slightly over 2.5 million, or 73 percent, of high-cost enrollees received Part D's low-income subsidy (LIS). That is, nearly 20 percent of LIS enrollees are high cost compared with less than 4 percent among non-LIS enrollees. Because LIS enrollees are more likely to be enrolled in prescription drug plans (PDPs), a large share of high-cost enrollees (75 percent) were in PDPs (data not shown). High-cost enrollees were also more likely to reside in an institution and be non-White disabled beneficiaries under age 65 compared with other enrollees (data not shown).

The number of high-cost enrollees has been rising since 2010, growing at an average annual rate of 10 percent between 2010 and 2014, compared with an annual average rate of 1 percent before 2010 (Table 14-13, p. 416). Gross spending above the catastrophic

(continued next page)

FIGURE 14–8 **Part D enrollees with spending in the coverage gap and catastrophic phase, 2014**



Note: ICL (initial coverage limit), OOP (out-of-pocket), LIS (low-income subsidy). Enrollees with spending between the ICL and the OOP threshold fall within Part D's coverage gap. LIS enrollees do not face a coverage gap because Medicare's low-income cost-sharing subsidy pays for what otherwise would be enrollee cost sharing. In 2014, Part D enrollees reached the ICL at $2,850 in gross drug spending. With no supplemental coverage, an enrollee reached the 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. Components may not sum to stated totals due to rounding.

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

Beneficiaries who reach the coverage gap or out-of-pocket threshold (cont.)

(i.e., out-of-pocket (OOP)) threshold also grew more rapidly during that period, rising at an annual 26 percent, compared with an annual 12 percent before 2010 (data not shown). Growth in the number of high-cost enrollees between 2010 and 2014 has been more rapid among non-LIS enrollees compared with LIS enrollees—24 percent annually compared with 6 percent annually.

Gross (or retail) prices affect enrollee cost sharing and the rate at which they reach the catastrophic phase of the benefit. As such, the trend in the number of high-cost enrollees appears to generally follow the (gross) price trend. For example, in 2012, when the Part D price index experienced its largest ever decline (–8.2 percent), the number of high-cost enrollees also declined (–1.4 percent). The uptick in prices observed after 2012 was accompanied by an increase in the number of high-cost enrollees, particularly among the non-LIS enrollees.

The growth of employer group waiver plans (EGWPs) and the Patient Protection and Affordable Care Act of 2010 (PPACA) OOP threshold changes have contributed to rapid growth in the number of non-LIS enrollees with high costs. From 2010 to 2014, the number of Part D enrollees increased as baby boomers began to retire and employers that had previously provided primary drug coverage to their former workers shifted their retirees to Part D by setting up EGWPs. Between 2010 and 2014, about 40 percent of the growth in the number of high-cost, non-LIS enrollees was due to growth in Part D EGWPs.[45] In addition, PPACA changes allowed manufacturers' discounts on brand-name drugs to count toward an enrollee's OOP spending in meeting the OOP threshold. ■

TABLE 14–13 **Part D enrollees reaching the benefit's catastrophic phase, 2007–2014**

							Average annual growth rate	
	2007	2010	2011	2012	2013	2014	2007–2010	2010–2014
In millions								
LIS	1.9	2.0	2.1	2.1	2.1	2.5	1%	6%
Non-LIS	0.4	0.4	0.5	0.5	0.7	0.9	–2	24
All	2.3	2.4	2.6	2.6	2.9	3.4	1	10

Note: LIS (low-income subsidy). Growth rates were calculated using figures before rounding was applied. Components may not sum to stated totals due to rounding.

Source: Enrollee counts from 2007 are based on published figures from CMS. Enrollee counts from 2010 to 2014 are based on MedPAC analysis of Part D prescription drug event data.

$50 to $25. Over the same period, the amount per member per month that sponsors expect to receive in reinsurance has grown 11.6 percent annually, from $26 to about $79. The expected reinsurance amount has increased more rapidly in recent years, growing by about 17 percent annually between 2013 and 2017.

High-cost enrollees driving overall Part D spending growth

The growth in Part D spending for reinsurance reflects the underlying trend that high-cost enrollees—those who reach the catastrophic phase of the benefit—have started to drive overall program spending. The share of

TABLE 14–14 **Spending for high-cost enrollees driving overall Part D spending, 2010–2014**

	2010	2014	Average annual growth rate, 2010–2014
High-cost enrollees			
Average price per 30-day prescription	$118	$166	8.8%
Prescriptions per enrollee per month	9.4	9.5	0.4
Gross drug spending per enrollee per month	$1,103	$1,570	9.2
Lower cost enrollees			
Average price per 30-day prescription	$41	$35	–3.9%
Prescriptions per enrollee per month	3.7	4.0	1.6
Gross drug spending per enrollee per month	$151	$138	–2.3
All Part D enrollees			
Average price per 30-day prescription	$55	$60	2.1%
Prescriptions per enrollee per month	4.2	4.5	1.6
Gross drug spending per enrollee per month	$231	$268	3.7

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

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

spending (including spending both above and below the OOP threshold) accounted for by high-cost enrollees has grown in recent years, from about 40 percent of the gross spending before 2011, to 44 percent in 2011, and to about 53 percent in 2014. As a result, average per capita spending across all Part D enrollees is increasingly affected by spending for high-cost enrollees. Between 2010 and 2014, per capita spending for all Part D enrollees grew an annual 3.7 percent (Table 14-14). That growth reflects an annual 9.2 percent increase for high-cost enrollees and an annual 2.3 percent decrease for enrollees who did not reach the OOP threshold.

Most of the growth in spending for high-cost enrollees is due to higher prices

Increases in the average price of prescriptions filled by high-cost enrollees have contributed to growth in their gross spending. That growth likely reflects increases in the prices of their medications, greater availability of higher priced drugs, and other changes in the mix of medications they were prescribed.

Between 2010 and 2014, the average price per standardized, 30-day prescription for high-cost enrollees grew at an average annual rate of 8.8 percent, while the number of prescriptions filled per enrollee per month grew an annual 0.4 percent (Table 14-14). That is, the growth in prices explains nearly all of the spending growth (9.2 percent) for high-cost enrollees during this period. This pattern is in stark contrast to enrollees who did not reach the OOP threshold. The average price per prescription for enrollees who did not reach the OOP threshold fell by an annual 3.9 percent, while the number of prescriptions used grew by a modest 1.6 percent per year. In other words, the change (decrease) in average per capita spending for these enrollees was driven by a decrease in the average price per prescription.

The higher growth in prices of drugs taken by high-cost enrollees can be partially explained by their tendency to use more brand-name drugs. For example, in 2014, the average generic dispensing rate (GDR) among high-cost enrollees was slightly less than 73 percent, or nearly 13 percentage points below the overall Part D average.

Drug classes used by high-cost enrollees

In 2014, 3.4 million high-cost enrollees (about 9 percent of all Part D enrollees) accounted for $64.6 billion, or 53 percent, of total gross spending under the Part D program. Ten therapeutic classes accounted for 60 percent of that total (Table 14-15). Some of the top 10 therapeutic classes coincide with those that are widely used by enrollees with lower drug spending, such as therapy agents to treat asthma or chronic obstructive pulmonary disease and antihyperlipidemics to treat high cholesterol.

Other therapeutic classes, such as antivirals and antineoplastics, are rarely used by enrollees with lower spending. Between 2013 and 2014, spending on antivirals for high-cost enrollees more than doubled, from $4 billion to $8.9 billion (data not shown). Most of that increase was attributable to the use of new hepatitis C drugs, which totaled about $4.6 billion in 2014.

Use of cancer treatments (antineoplastics) was more prevalent among high-cost, non-LIS enrollees, accounting for more than 20 percent of their spending, compared with less than 5 percent among high-cost enrollees with LIS (not all therapeutic classes used for cancer treatments are shown in the table). Other notable differences between the therapeutic classes that are heavily used by high-cost enrollees with and without the LIS include heavy use of antipsychotics and peptic ulcer therapies (data not shown). Enrollees with the LIS accounted for over 90 percent of high-cost enrollee spending for these two classes. For certain drug classes, underlying differences in health status, such as a higher prevalence of behavioral health conditions, may explain much of this use by LIS enrollees. ■

TABLE 14–15 **Top 10 drug classes used by high-cost enrollees, by spending, 2014**

		Share of spending by high-cost enrollees		
	Drug class	**All**	**LIS**	**Non-LIS**
1	Antivirals	14%	15%	11%
2	Diabetic therapy	11	11	10
3	Antipsychotics (neuroleptics)	8	11	<2
4	Antineoplastic–systemic enzyme inhibitors	5	3	11
5	Asthma/COPD therapy agents	5	6	4
6	Analgesic, anti-inflammatory or antipyretic—Non-narcotic	5	4	6
7	Analgesics—Narcotic	3	4	2
8	Antihypertensive therapy agents	3	3	4
9	Anticonvulsants	3	4	<2
10	Antihyperlipidemics	3	3	3
Total top 10 classes for all high-cost enrollees		60	60	55
Total gross spending, billions		$64.6	$43.1	$21.5

Note: LIS (low-income subsidy), COPD (chronic obstructive pulmonary disease). Spending includes all payments to pharmacies, including payments by drug plans, Medicare's low-income subsidy, and beneficiary out of pocket. Therapeutic classification is based on the First DataBank Enhanced Therapeutic Classification System 1.0.

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

TABLE 14–16

High-cost enrollees and their prescription use and spending, 2014

	High-cost enrollees		
		LIS status	
	All	LIS	Non-LIS
Beneficiaries, in millions	3.4	2.5	0.9
Share of total for high-cost enrollees		73%	27%
Total gross spending, in billions of dollars	$64.6	$43.1	$21.5
Share of total for high-cost enrollees		67%	33%
Total numbers of 30-day prescriptions, in millions	390.4	296.7	93.7
Share of total for high-cost enrollees		76%	24%
Gross annual spending per enrollee, in dollars	$18,845	$17,222	$23,247
Average number of prescriptions per enrollee	114	118	101
Average price per prescription, in dollars	$166	$145	$229
Average annual OOP spending per enrollee	$837	$116	$2,794

Note: LIS (low-income subsidy), OOP (out-of-pocket). Components may not sum to totals due to rounding. A beneficiary is classified as "LIS" if that individual received Part D's LIS at some point during the year. Numbers of prescriptions are standardized to a 30-day supply.

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

Some of the difference reflects situations in which brand-name medications are the dominant standard of care for a therapeutic drug class. Prices of many brand-name drugs that do not have generic substitutes are typically much higher and grow more rapidly compared with other drug products.

While generic substitution is not available for certain classes of drugs, many of the drugs used by high-cost enrollees are the same as those used heavily by all Part D enrollees (see text box on drug classes used by high-cost enrollees). For example, antihypertensive therapy agents for high blood pressure and antihyperlipidemics to treat high cholesterol are both classes of drugs commonly used by all Part D enrollees, including those who reach the OOP threshold. We have consistently found that high-cost enrollees tend to use more brand-name drugs than other enrollees, even in classes with generic substitutes. This lower GDR is due, in part, to the fact that most high-cost enrollees are individuals who receive the LIS. The cost-sharing subsidy, while helping these beneficiaries to afford medications, also minimizes or eliminates the financial incentives plans employ to encourage the use of lower cost drugs. One of the Commission's June 2016 recommendations was intended to encourage LIS enrollees to use lower cost alternatives (including generic drugs and biosimilars) when they are available through moderate changes to financial incentives (see text box on the Commission's June 2016 recommendations, p. 389).

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

Patterns of drug spending among high-cost enrollees vary depending on LIS status. For example, in 2013, of the 20 therapeutic classes that accounted for about 80 percent of spending by high-cost LIS enrollees, only 4 classes (e.g., antineoplastics and multiple sclerosis agents) were typically associated with specialty-tier drugs or biologic products. Spending for drugs in those four classes accounted for less than 8 percent of high-cost LIS enrollees' total spending compared with nearly 30 percent of spending by high-cost enrollees without the LIS. This pattern is reflected in the higher average spending in 2014 by high-cost enrollees without the LIS: $229 per prescription and $23,247 per year compared with $145 per prescription and $17,222 per year for high-cost enrollees with the LIS (Table 14-16).

High-cost LIS enrollees pay lower cost sharing out of pocket than high-cost non-LIS enrollees. Average annual OOP cost-sharing amounts for high-cost LIS enrollees were $116 compared with $2,794 among non-LIS enrollees. One might expect average annual OOP spending for high-cost non-LIS enrollees to be higher than $4,550, which was Part D's OOP threshold in 2014. The average amount is lower primarily because those enrollees received credit that counted as OOP spending for the 50 percent discount provided by brand-name manufacturers in the coverage gap.

Use of higher cost drugs poses challenges for Part D

Drugs with very high prices pose a particular challenge for Part D. As more expensive therapies become available, larger numbers of beneficiaries will reach the catastrophic phase of the benefit, when Medicare pays for 80 percent of the costs through individual reinsurance. The use of higher cost drugs and biologics has already been growing rapidly in the last few years. Between 2010 and 2014, the use of drugs placed on specialty tiers has grown by an annual average of more than 20 percent, compared with about 2 percent before 2010. In general, spending for high-cost drugs has grown rapidly in the last few years. Between 2010 and 2015, drugs with average monthly prices of $1,000 or more accounted for two-thirds of spending in the catastrophic phase of the benefit in 2015 compared with just one-third in 2010 (Office of Inspector General 2017).

For the future, the high and increasing cost of specialty drugs poses a big challenge in Part D because these drugs are concentrated in drug classes that treat conditions that are prevalent in the Medicare population such as rheumatoid arthritis and other inflammatory diseases, cancer, and HIV (Express Scripts 2014). Many payers project that growth in price and use of specialty drugs will continue to drive trends in spending.[46] In the drug pipeline, fewer blockbuster drugs face expiring patents, and more than half of the FDA's approvals of new drugs in 2013 were for specialty drugs (CatamaranRx 2014). Because many of these therapies have few substitutes, prices for specialty drugs tend to be high, affording PBMs and insurers less ability to exert downward pressure on price.

As the use of specialty drugs increases, Part D enrollees and the Medicare program will face increasingly higher costs. Coinsurance on high-priced medicines could become so burdensome that some non-LIS enrollees could be discouraged from initiating or completing treatment.[47]

If larger numbers of beneficiaries begin to use specialty drugs at the same time that Part D's coverage gap is eliminated, the number who reach the OOP threshold will continue to rise. In turn, Medicare spending for individual reinsurance and low-income cost sharing will also rise.

Beneficiaries' access to prescription drugs

A key goal for the Part D program is to provide Medicare beneficiaries with good access to clinically appropriate medications while remaining financially sustainable to taxpayers. That goal involves finding a balance between managing medication therapies to encourage adherence to drugs with good therapeutic value while being judicious about whether the overall number and mix of medicines prescribed is beneficial to a particular patient (Medicare Payment Advisory Commission 2016c). Formulary management is one of the most important tools used by plan sponsors to strike this balance.

Greater flexibility to use management tools could help ensure that prescribed medicines are safe and appropriate for the patient, potentially reducing overuse and misuse. However, for some beneficiaries, those same tools could also limit access to needed medications. To ensure beneficiary access, CMS reviews and approves each plan's formulary to ensure that Part D plans are providing good access to a wide range of therapeutic classes used by the Medicare population. Part D law also requires sponsors to have a transition process to ensure that new enrollees, as well as current members whose drugs are no longer covered or are subject to new restrictions, have access to the medicines they have already been taking.[48] Medicare requires plan sponsors to establish coverage determination and appeals processes with the explicit goal of ensuring that plan formularies do not impede access to needed medications.

Part D's exceptions and appeals process

Part D's exceptions and appeals process is complex, involving multiple levels (Medicare Payment Advisory Commission 2014b). It begins when an enrollee's prescription is denied at the pharmacy because of a plan's utilization management or cost-sharing requirements, or because the drug is not listed on the plan's formulary. The pharmacy is required to provide the enrollee with written information on how to obtain a detailed written notice from the enrollee's plan about why the benefit was

denied and the right to appeal. To initiate a request for an appeal, the enrollee must contact the plan for the basis of the denial of benefits and initiate a request for a coverage determination with supporting justification from the prescriber.

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

After examining Part D's exceptions and appeals process, we found insufficient data to evaluate how well the process is working for beneficiaries to gain access to needed medications (Medicare Payment Advisory Commission 2015b, Medicare Payment Advisory Commission 2014b). We also found that the process can be time consuming and frustrating and is burdensome for some individuals (Hargrave et al. 2015, Hargrave et al. 2012). CMS continues to find that a significant share of audited plans have difficulties in the areas of Part D transition fills, coverage determinations, appeals, and grievances. For example, a common shortfall is that many plans provide enrollees with too little information about the rationale for a coverage denial or do not demonstrate that they have reached out to prescribers for additional information to make a coverage decision (Centers for Medicare & Medicaid Services 2016f). At the start of benefit year 2016, CMS applied intermediate sanctions against several Part D plan sponsors for failure to comply with regulations in multiple areas, including Part D formulary and benefit administration and Part D coverage determinations, appeals, and grievances (Centers for Medicare & Medicaid Services 2017b). The sanctions imposed immediate suspension of marketing to and enrollment of Medicare beneficiaries, and they remain in effect until corrective actions are taken.

At the same time, exceptions and appeals that routinely overturn plans' coverage decisions could undermine plans' efforts to manage drug spending. A plan sponsor's representative described for us the sponsor's experience in which the plan's decisions denying coverage of drugs because they were not on the plan's formulary were routinely overturned by an independent review entity (IRE). The plan sponsor was generally not successful in appealing IRE decisions; appeals were typically denied on the grounds that supporting statements provided by prescribers proved the medical necessity for the drug—even when those statements were extremely general such as, "this is the right drug for the patient." Because a Part D plan's star rating includes how often its coverage decisions are overturned by the IRE, such cases can have a chilling effect on a plan's willingness to use formulary tools—including on-formulary or off-formulary status—to manage the use of expensive medications. That reluctance to use formulary tools, in turn, can affect the rebate negotiations with pharmaceutical manufacturers.

In our discussions, stakeholders—beneficiary advocates, prescribers, plan sponsors, and CMS—have all noted frustrations with Part D coverage determinations, exceptions, and appeals. A more efficient approach would be to resolve such issues at the point of prescribing through e-prescribing and electronic prior authorization rather than at the pharmacy counter. Such tools could reduce the need for coverage determinations and appeals and increase the likelihood that beneficiaries receive an appropriate medicine at the pharmacy. Automated processes could also lower the administrative burden and lead to a more uniform approach for beneficiaries, prescribers, and plans (American Medical Association 2015). Part D plan sponsors are required to support electronic prescribing, but e-prescribing is optional for physicians and pharmacies.[49] While beneficiary advocates are generally supportive of such steps, some contend that they would not be sufficient to address persistent challenges (Medicare Rights Center 2016).

Quality in Part D

CMS collects quality and performance data to monitor sponsors' operations. A subset of data is used to rate plans in a 5-star system, from which CMS determines Medicare Advantage (MA) quality bonus payments (quality bonus payments do not apply to stand-alone PDPs). Quality data are also made available to the public to help beneficiaries evaluate their plan options during Part D's annual open enrollment. CMS also requires plan sponsors to carry out

medication therapy management (MTM) programs to improve the quality of the pharmaceutical care for high-risk beneficiaries. Although the Commission supports CMS's goal of improving medication management, we have ongoing concerns about the effectiveness of plans' MTM programs. In 2017, CMS began a new enhanced MTM model. We plan to examine the effectiveness of the new MTM program once additional information becomes available.

Measuring plan performance

CMS collects Part D plan quality and performance data from several sources—the Consumer Assessment of Healthcare Providers and Systems® (CAHPS®) survey, agency monitoring of plans, data furnished by plan sponsors, and claims information (Centers for Medicare & Medicaid Services 2014c). Selected performance measures are available on the Plan Finder at www.medicare.gov to help beneficiaries evaluate their plan options during Part D's annual open enrollment. The lowest rated plans are 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 MA program's overall plan ratings to determine the amount of bonus payment.

For 2017, Part D plan ratings are based on up to 15 metrics that measure plan performance on intermediate outcomes, patient experience and access, and process (Centers for Medicare & Medicaid Services 2016c). Intermediate outcome measures (four metrics, e.g., adherence to selected class of medications) each receive a weight of 3, while the eight measures related to patient experience and access (e.g., CAHPS survey results on ease with which plan members get needed medicines) each receive a weight of 1.5. Two process measures (e.g., accuracy of drug prices posted on the Plan Finder) receive a weight of 1. Finally, drug plan quality improvement, a measure reflecting changes in drug plans' performance from one year to the next, is assigned the highest weight (5). Most MA–PDs are rated on up to 32 measures that assess the quality of medical services provided under Part C (i.e., the MA program), in addition to the 15 measures used to assess the quality of prescription drug (Part D) services provided. CMS aggregates individual scores for each measure (15 for PDPs and 44 for MA–PDs) on the Plan Finder in a 5-star system; 5 stars reflects excellent performance, and 1 star reflects poor performance.

Among PDPs, the average star rating for 2017 (weighted by 2016 enrollment) increased to 3.55 from 3.40 a year earlier (Centers for Medicare & Medicaid Services 2016c). About 40 percent of PDP enrollees (based on the 2016 enrollment) are in contracts with 4 or more stars. Among MA–PDs offered for 2017, the average star rating remained stable at 4.00. (See the Medicare Advantage chapter for a discussion of star ratings for MA plans and MA–PDs.) About 68 percent of MA–PD enrollees are in contracts with 4 or more stars.

Star ratings could provide useful information when enrollees are choosing among plan options or when plan sponsors are evaluating certain areas for improvement. However, none of the beneficiaries who participated in the Commission's focus groups mentioned using the Medicare star ratings as a source of information to choose a health plan (Wesolowski 2016). Further, the utility of star ratings to measure quality of prescription drug services tends to be limited. For example, one measure of intermediate outcomes in star ratings is use of high-risk medications (HRMs). The measure is defined as the share of beneficiaries 65 years and older who received two or more prescription fills for the same drug with a high risk of serious side effects in the elderly (Centers for Medicare & Medicaid Services 2016h). CMS notes that while its HRM measure is endorsed by both the Pharmacy Quality Alliance and National Quality Forum, "the addition of a drug to the HRM list is not a contraindication to use, rather an encouragement to avoid use in the senior population without consideration of risks and benefits based on individual patient characteristics" (Centers for Medicare & Medicaid Services 2016e). Because quality measures calculated only from prescription claims (i.e., without the corresponding medical claim(s)) cannot account for all clinically relevant factors, such a metric "may create unintended consequences including the inappropriate encouragement of certain non-HRM medications, which may not be the best choice for an individual beneficiary's clinical circumstances" (Centers for Medicare & Medicaid Services 2016e). Further, changes in the composition of the measures CMS uses to rate plans over the years makes it difficult to use the star ratings to measure changes in quality of services provided by plans over time.

Medication therapy management programs

Part D plans are required to implement MTM programs to improve the quality of the pharmaceutical care for beneficiaries who may be at risk for adverse drug events, including adverse drug interactions. These programs are

intended to optimize therapeutic outcomes and reduce adverse drug events through improved medication use among beneficiaries who have multiple chronic conditions, take multiple medications, and are likely to have annual drug spending that exceeds the annual cost threshold ($3,919 for 2017). Our earlier review of MTM programs revealed wide variations in eligibility criteria and the kinds of interventions provided to enrollees (Medicare Payment Advisory Commission 2009).

Plan sponsors are required to offer all eligible enrollees a comprehensive medication review (CMR) at least annually and a targeted medication review (TMR) at least quarterly for ongoing monitoring and follow-up of any medication-related issues.[50] CMS has changed criteria for plans' MTM programs over time to broaden eligibility. Currently, plan sponsors can no longer set narrower eligibility criteria than requiring beneficiaries to have more than three chronic conditions or use more than eight medications. Eligible enrollees must opt out of participation.

Although the Commission supports CMS's goal of improving medication management, we have long-standing concerns about the overall outreach and effectiveness of Part D's MTM program. As CMS has noted in the past, plans are often unable to reach eligible beneficiaries, and many refuse the service. In 2014, 11.9 percent of Part D enrollees were eligible for MTM services using Part D's standard criteria, and another 0.7 percent were eligible through expanded plan-specific criteria (Centers for Medicare & Medicaid Services 2016k). Among those eligible for the services that year, 19 percent received a CMR, or just 2 percent of all Part D enrollees. A recent analysis of MTM programs found wide variation in participation across sponsors and plans. The authors contend that most sponsors have chosen to offer services to a narrow segment of enrollees, missing opportunities to improve medication management (Stuart et al. 2016). A concern is that sponsors of stand-alone PDPs do not have financial incentives to engage in MTM or other activities that, for example, increase adherence to appropriate medications. In addition, physicians may be reluctant to accept recommendations from drug plans with which they have no direct relationship. Evidence suggests that the effectiveness of the MTM services currently offered by Part D plans "fall[s] short of their potential to improve quality and reduce unnecessary medical expenditures" (Centers for Medicare & Medicaid Services 2015c, Marrufo et al. 2013).

In 2017, CMS began an enhanced MTM model in five regions of the country to test whether payment incentives and greater regulatory flexibility in designing MTM programs will "achieve better alignment of PDP sponsor and government financial interests, while also creating incentives for robust investment and innovation in better MTM targeting and interventions" (Center for Medicare & Medicaid Innovation 2015). Regulatory flexibility combined with financial incentives provided under the model have the potential to address some of the Commission's concerns regarding coordination with a beneficiary's care team and plans' incentive to offer MTM programs (Medicare Payment Advisory Commission 2014a) (see text box, p. 424). We plan to continue to monitor how well the current MTM program is working and report on the new enhanced MTM model as more information becomes available. ■

2017 launch of enhanced medication therapy management

Six Part D sponsors operating prescription drug plans (PDPs) in five regions of the country are participating in CMS's enhanced medication therapy management (MTM) model over a five-year period.[51] (Not every sponsor is participating in each region.) An estimated 1.6 million enrollees will be eligible to participate in the first year (Centers for Medicare & Medicaid Services 2016l). Part D's program requirements related to uniformity of benefits and cost sharing will be waived for participating PDPs, which would provide plan sponsors with the ability to offer MTM interventions tailored to an individual's needs, including cost-sharing assistance to financially needy beneficiaries (Centers for Medicare & Medicaid Services 2015c).

CMS's stated goal is for the participating PDPs to explore different communication strategies to improve beneficiary, pharmacist, and medical provider coordination and engagement. To aid that effort, CMS can provide participating PDPs with their enrollees' Part A and Part B claims data and information on beneficiaries' participation in integrated care models such as accountable care organizations (Center for Medicare & Medicaid Innovation 2017).

Because stand-alone PDPs may not necessarily benefit financially from providing MTM services that could improve enrollees' health outcomes and lower costs for the Medicare program, the model test also includes financial incentives for participating PDPs:

- a plan-specific prospective payment for MTM services that is outside the annual Part D bid and does not therefore impact plan premiums and
- a performance-based payment in the form of an increased beneficiary premium subsidy (in a future year) for plans that successfully achieve a 2 percent reduction in expected beneficiary fee-for-service expenditures (net of model prospective payments).

Sponsors participating in the enhanced MTM model will be required to collect and submit MTM-related encounter data for both monitoring and evaluation purposes, including "whether the plan interventions are correlated with outcomes such as mortality, emergency department utilization, hospital readmissions, or beneficiary satisfaction measures" (Centers for Medicare & Medicaid Services 2016l). ■

Endnotes

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

2 Table II.B.1 of the Medicare Trustees' 2016 report lists Part D expenditures for 2015 as $89.8 billion (Boards of Trustees 2016). That larger amount includes reconciliation payments made during 2015 between Medicare and plan sponsors for benefits delivered in previous years.

3 In 2017, the Part D benefit provides gap coverage of 10 percent for brand-name drugs, in addition to a 50 percent discount provided by drug manufacturers, reducing cost sharing in the gap to about 40 percent (Centers for Medicare & Medicaid Services 2016e). Cost sharing for brand-name drugs filled depends on the dispensing fee charged since the 10 percent covered by Part D applies to both the ingredient cost and the dispensing fee, while the 50 percent manufacturer discount applies only to ingredient costs.

4 CMS's de minimus policy (codified under Section 3303(a) of PPACA) allows plan sponsors to voluntarily waive the portion of the monthly adjusted basic beneficiary premium that is above the low-income subsidy (LIS) benchmark for a subsidy-eligible individual, up to a de minimis amount (Centers for Medicare & Medicaid Services 2016i). The de minimis amount for 2017 is $2.

5 The Commission recommended removing protected status from two out of the six drug classes in which plan sponsors must now cover all drugs on their formularies (antidepressants and immunosuppressants for transplant rejection), streamlining the process for formulary changes, requiring prescribers to provide supporting justifications with more clinical rigor when applying for exceptions, and permitting plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications (Medicare Payment Advisory Commission 2016c).

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

7 Other sources of coverage include the Federal Employees Health Benefits Program, TRICARE for Life, and the Department of Veterans Affairs.

8 Employer group waiver plans, or EGWPs, are Part D plans sponsored by employers that contract directly with CMS or with an insurer or a pharmacy benefit manager to administer a drug benefit on the employer's behalf. EGWPs differ from employer plans that receive the RDS in that they are considered Part D plans; that is, Medicare Part D is the primary payer rather than the employer. However, unlike other Part D plans, EGWPs are offered only to Medicare-eligible retirees of a particular employer (i.e., the requirement that anyone be allowed to enroll in such a plan is waived).

9 Under the Part C payment system, a portion 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.

10 Extra coverage in the gap (beyond what is required by the PPACA) is typically restricted to a subset of formulary drugs.

11 MA–PD premiums reflect Medicare Advantage plans' total monthly premium attributable to Part D benefits for plans that offer Part D coverage. The premiums are net of Part C rebate dollars that were used to offset Part D premium costs.

12 CMS allows sponsors to offer several plans in a given service area if the plans are "meaningfully different." To be considered meaningfully different for 2017, a beneficiary's expected OOP costs between basic and enhanced PDPs must differ by at least $23 per month. If a sponsor is offering two enhanced PDPs in the same service area, the second plan must have a higher value than the first, with an OOP difference of at least $34 per month.

13 Twenty-five of the benchmark plans are offered by Cigna-HealthSpring Rx, which CMS currently has placed under sanction, meaning that those plans cannot accept new enrollees.

14 More than half of LIS enrollees who paid a premium in 2016 were in enhanced plans (Hoadley et al. 2016).

15 The company itself is a product of the acquisition of the PBM Caremark by CVS in 2007. Since the beginning of Part D, CVS Health acquired Longs Drug Stores' RxAmerica plans,

Universal American's Community CCRx and Pennsylvania Life product lines, and Health Net Orange PDPs.

16 Another plan sponsor with large numbers of LIS enrollees is Rite Aid. That company became a plan sponsor in 2015 when it acquired EnvisionRx, a PBM that was already participating in Part D. In 2016, 76 percent of Rite Aid's enrollees (0.3 million) received the LIS, and plans offered by Rite Aid accounted for 2 percent of all LIS enrollment. Rite Aid currently operates a chain of about 4,600 drugstores and is due to be acquired by Walgreens Boots Alliance, which operates 8,200 U.S. drugstores (Mattioli et al. 2015). The merger has been under regulatory review and is scheduled to close in 2017.

17 Some in-house PBMs also provide PBM services under contract to other payers. For example, OptumRx has won recent contracts with General Electric and the California Public Employees' Retirement System.

18 PBMs can earn revenues in a number of ways, including administrative fees from payers and manufacturers, retaining a portion of manufacturers' rebates, and through the "spread" between what the PBM receives from a payer for a prescription and what the PBM pays the pharmacy. Under newer arrangements for conditions such as hepatitis C, PBMs may refund drug costs to payers if a patient is not adherent to treatment (Rubenfire 2016). Some investment analysts contend that over time, a greater share of PBM revenue has come from administrative fees than from rebates and spread. Critics of the industry argue that the opacity of drug pricing and rebates makes it difficult to monitor whether the PBM is obtaining the lowest prices possible and sharing revenues appropriately with clients (Applied Policy 2015). PBMs counter that their contracts provide transparency and pass along rebates to the extent demanded in the competitive market and in response to negotiations with individual clients.

19 A recent dispute between one major insurer and its PBM over repricing provisions in their 10-year contract has been acrimonious. In 2009, Express Scripts purchased Anthem's (then WellPoint's) in-house PBM, NextRx (Anthem 2009). As part of the agreement, Anthem signed a 10-year contract to use Express Scripts as its PBM. In March 2016, Anthem filed suit against Express Scripts for pricing and operational contract breaches, requesting damages of $13 billion and permission to end the contract (Silverman 2016). Express Scripts filed a countersuit, alleging that Anthem did not negotiate repricing in good faith (Walker 2016). In July 2016, a lawsuit against both Anthem and Express Scripts seeking class-action status was launched on behalf of insured employees whose employers used the services of Anthem. The suit alleges that insured employees paid too much because of "above competitive pricing levels" (Appleby 2016). Express Scripts and Anthem both deny the allegations.

20 When using a mail pharmacy, enrollees generally receive a 90-day rather than a 30-day prescription.

21 CVS Health purchased the nation's largest long-term care pharmacy company, Omnicare, in 2015.

22 The six protected classes include anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection.

23 For 2017, CMS permits plans to place a drug on a specialty tier if its average cost is at least $670 per month. If a plan uses the same deductible as in Part D's defined standard benefit, it must charge 25 percent coinsurance for drugs on its specialty tier. Plans with no deductible may charge up to 33 percent coinsurance on their specialty tier.

24 These measures need to be used with caution because they can be misleading in some circumstances. For example, some plan sponsors list relatively few drugs on their formulary but have an exceptions process that permits good access to other medications. Alternatively, other sponsors list most drugs on their formulary but require prior authorization for a relatively larger number of drugs.

25 For this calculation, we define drugs at the level of chemical entities—a broad grouping that encompasses all of a chemical's forms, strengths, and package sizes—that combine brand and generic versions of the same specific chemical entity (Medicare Payment Advisory Commission 2008).

26 Recent controversy over price growth for certain brand-name drugs has led to concern about the use of rebates. According to one analysis, list prices for the epinephrine autoinjection device EpiPen grew by 150 percent between 2013 and 2016 (CVS Health 2016). The EpiPen drew attention because commercially insured individuals in high-deductible plans often pay for full increases in list prices. However, the chief executive officer of Mylan (EpiPen's manufacturer) defended the company's pricing on the grounds that net prices (that is, list prices after rebates to PBMs and payments to wholesalers and distributors) were substantially smaller (Bresch 2016). PBMs counter that the price concessions they negotiate lower overall costs to the health care system (*American Pharmacy News* 2016).

27 After 2020, in the range of spending that was formerly the coverage gap, manufacturers of brand-name drugs will continue to provide a 50 percent discount and plan sponsors will be liable only for 25 percent of spending, compared with plan liability of 75 percent between the deductible and initial coverage limit.

28 Note that, if many enrollees used certain drugs with higher list prices, it could affect the share of rebates and pharmacy fees that Medicare would keep, and correspondingly could affect plan costs.

29 However, if the cost of dispensing an extended supply is higher at the retail pharmacy, the plan sponsor can charge the enrollee cost sharing that is higher by as much as that cost differential.

30 Some pharmacies may choose not to contract with certain plans because they do not like the terms and conditions the plans offer. Plan sponsors are not obligated to cover prescriptions at an out-of-network pharmacy, except under certain circumstances.

31 The minimum standard for pharmacy network access, based on the TRICARE standard, is as follows—urban areas: at least 90 percent of Medicare beneficiaries in the sponsor's service area reside within 2 miles of a network retail pharmacy; suburban areas: at least 90 percent of Medicare beneficiaries in the sponsor's service area reside within 5 miles of a network retail pharmacy; rural areas: at least 70 percent of Medicare beneficiaries in the sponsor's service area reside within 15 miles of a network retail pharmacy.

32 The Commission has expressed support for plan innovations that increase efficiency, and we agree with CMS that the competition created by preferred pharmacy networks should result in lower costs for the program and for Part D enrollees. However, we noted in a 2014 comment letter to CMS that a separate pharmacy access standard may be required to ensure that plan enrollees have reasonable access to preferred cost sharing (Medicare Payment Advisory Commission 2014a).

33 Part D enrollees may apply to bona fide independent charity patient assistance programs (PAPs) for help with cost sharing. Pharmaceutical manufacturers can provide cash donations to independent charity PAPs without invoking anti-kickback concerns if the charity is structured properly. Guidance from the Department of Health and Human Services Office of Inspector General states that independent charity PAPs must provide assistance to broad rather than narrow disease groups, manufacturers must not exert direct or indirect control over the charity, and the PAP must not limit assistance to a subset of available products (Office of Inspector General 2014).

34 A Risk Evaluation and Mitigation Strategy describes measures beyond labeling that are sometimes required as a condition of FDA approval to ensure that a new drug is dispensed to patients for whom benefits outweigh risks.

35 As of 2013, 66 percent of commercial health plans mandate that self-administered specialty drugs be dispensed by a specialty pharmacy, and about three-quarters of health plans require beneficiaries to use designated specialty pharmacy providers (Fein 2015).

36 A specific concern raised by independent specialty pharmacies is that plans and PBMs are using performance-based criteria that do not apply to the types of drugs they dispense, such as adherence to drugs for treatment of cholesterol or diabetes.

37 The industry does not have one consistent definition of specialty drugs, but these drugs tend to be characterized as high cost and are used to treat a rare condition, require special handling, use a limited distribution network, or require ongoing clinical assessment. Most biologics are a subset of specialty drugs (see *American Journal of Managed Care* 2013).

38 These figures are based on the Acumen LLC analysis of the Part D prescription drug event data for the Commission. Most plans use specialty tiers for drugs and biologic products that meet the dollar per month cost threshold ($670 in 2017) set by CMS. A specialty-tier drug is different from a specialty drug in that it is identified based on its placement on a plan's specialty tier and varies across plans. Typically, plans charge enrollees coinsurance of 25 percent to 33 percent for drugs placed on specialty tiers.

39 IMS Health defines invoice prices as the amounts paid to distributors by their pharmacy or hospital customers, which is different from gross spending reflected in Part D's prescription drug event data (total payments to pharmacies before accounting for any rebates or discounts pharmacies retain). Net prices measure the amount received by pharmaceutical manufacturers and therefore reflect rebates, off-invoice discounts, and other price concessions made by manufacturers to distributors, health plans, and intermediaries.

40 An individual NDC uniquely identifies the drug's labeler, drug, dosage form, strength, and package size. Typically, the same drug has many different NDCs.

41 For this index, Acumen grouped 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.

42 Differences in GDRs vary by therapeutic classes. In 2012, for some of the most commonly used classes of drugs, the average GDR for LIS enrollees was from 5 percentage points to 13 percentage points lower than for non-LIS enrollees. We observed this finding in both PDPs and MA–PDs.

43 For benefits delivered in 2014 and 2015, the majority of the plan sponsors received additional individual reinsurance payments from Medicare at reconciliation, much of which was because of higher than anticipated spending on new hepatitis C therapies and the continuing growth in cost for specialty drugs (Boards of Trustees 2016). Even with that unexpectedly higher spending, most plan sponsors made risk-corridor payments to Medicare.

44 Our analysis is based on CMS's dashboard. CMS's data excludes claims for all over-the-counter drugs.

45 The Patient Protection and Affordable Care Act of 2010 changed the tax treatment of Medicare's retiree drug subsidy and made the Part D benefit more generous through the phased closure of the coverage gap and the provision of brand discounts. These changes in the law likely motivated employers that had previously provided primary drug coverage to their former workers to move their retirees into Part D by setting up employer group waiver plans for them.

46 Among PBMs, growth in price and use of specialty drugs has been driving the overall trend in spending. Across their entire non-Medicare and Medicare books of business, PBMs' spending on specialty drugs reached about 30 percent in 2012 and may reach 50 percent of spending by 2018 (Seeking Alpha 2013).

47 Recall that enrollees typically face coinsurance of 25 percent to 33 percent until they reach the catastrophic phase of the benefit.

48 The transition fill is a temporary one-time supply of up to 30 days of medication provided during the first 90 days in a plan for new enrollees and during the first 90 days of the new contract year for existing enrollees. For individuals living in long-term care facilities, the temporary supply may be for up to 31 days and may be renewed as necessary during the entire length of the 90-day transition period. Each year since 2012, CMS has conducted a transition monitoring program analysis to evaluate whether plan sponsors are following Part D transition requirements. In 2016, 6 percent of Part D contracts exceeded CMS's thresholds of noncompliance (Centers for Medicare & Medicaid Services 2016j).

49 The exception is New York, which mandates electronic prescribing.

50 CMRs must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider and a written summary of the review that includes a medication list and action plan, if any, provided to beneficiaries in CMS's standardized format. In 2014, 85 percent of CMRs were conducted by pharmacists over the telephone (Centers for Medicare & Medicaid Services 2016k). A TMR is distinct from a CMR because it is focused on specific medication-related problems, actual or potential. A TMR can be person to person or system generated, and interventions can be delivered by mail or faxed to the beneficiary or the prescriber, as appropriate (Centers for Medicare & Medicaid Services 2014b).

51 Participating plans are basic PDPs in the following five regions: Region 7 (Virginia), Region 11 (Florida), Region 21 (Louisiana), Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming), and Region 28 (Arizona) (Centers for Medicare & Medicaid Services 2016l).

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