Competition and the Cost of Medicare’s Prescription Drug Program
Notes

Unless otherwise indicated, all years referred to in this report are calendar years.

Numbers in the text and tables may not add up to totals because of rounding.

This report analyzes Medicare Part D, which covers outpatient prescription drugs, from 2006 to 2010. However, 2006 is excluded from much of the analysis because it was the first year of the Part D program and many enrollees did not have coverage for the full year, which makes cross-year comparisons difficult. When CBO completed this analysis, the detailed data used in the analysis were not available for years beyond 2010.

Throughout this report, total spending for a Medicare Part D beneficiary consists of all drug spending by the beneficiary, the federal government, and the beneficiary’s drug plan for outpatient drugs eligible for coverage by Part D, regardless of whether that spending is paid for by the Part D benefit. Drugs for patients who are staying in hospitals are covered by Medicare Part A, and certain drugs, primarily those administered in physicians’ offices or in hospital outpatient settings, are covered by Medicare Part B.
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The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (generally referred to as the Medicare Modernization Act, or MMA) substantially expanded the federal Medicare program by creating the prescription drug benefit known as Part D. In fiscal year 2013, Medicare Part D covered 39 million people. The federal government spent $59 billion net of premiums on Part D in that year; after accounting for certain payments from states under the program, the net federal cost was $50 billion, which represented 10 percent of net federal spending for Medicare. A combination of broader trends in the prescription drug market and lower-than-expected enrollment in Part D has contributed to much lower spending for the program—about 50 percent lower in 2013—than the Congressional Budget Office (CBO) projected when the MMA became law in 2003.

Most beneficiaries of Part D choose among private drug plans to receive their coverage; others have employment-based coverage subsidized by Medicare Part D. The competitive design of Part D enables it to adapt flexibly to changing conditions, because plan sponsors (private insurance firms, each of which may offer several different plans) have ongoing incentives to develop new ways to control drug spending so as to minimize their costs, keep premiums low, and attract enrollees. Using the first few years of data from the Part D program, CBO found that spending was lower in years when, and in areas of the country where, more plan sponsors competed for beneficiaries. CBO’s analysis suggests that competition between plan sponsors in Part D could be strengthened further, and costs lowered further, through certain changes in the rules of the program, although such changes could have disadvantages as well.

Other government programs use different approaches to deliver prescription drug benefits and hold down the costs of those benefits. In particular, the joint federal-state Medicaid program does not rely on competition between plan sponsors to constrain drug costs; instead, the program’s chief cost management tool is statutory rebates that are applied to market-based prices. CBO found that Medicaid pays lower prices than Medicare, on average, for the mix of prescription drugs purchased by Medicare enrollees, primarily because the rebates that the law requires on brand-name drugs under Medicaid are larger than the ones that plan sponsors negotiate with manufacturers under Part D. If policymakers implemented Medicaid’s statutory rebates for Part D beneficiaries with low income, but otherwise left Part D unchanged, federal costs would be reduced substantially in the short term. However, firms would respond by charging higher prices before rebates for new drugs (thereby probably offsetting a substantial portion of the savings for the federal government over the longer term) and by curtailing drug innovation.

Why Has the Part D Program Cost Less Than Anticipated?

Broad national trends in the prescription drug market have contributed significantly to the lower-than-expected spending for Part D. Many health care analysts, including those at CBO, expected in 2003 that growth in national drug spending would slow from the rapid rates observed in the late 1990s and early 2000s, but the magnitude of the slowdown that began after 2003 caused national drug spending in 2012 to be about 40 percent less than the amount predicted by analysts at the Centers for Medicare & Medicaid Services in 2003.

CBO
Two developments accounted for much of the slowdown in growth of national drug spending per person:

- Many existing brand-name drugs lost their patent protection and faced new competition from generic substitutes, which have the same active ingredients as their brand-name counterparts but are much less expensive. Between 2007 and 2010, the share of prescriptions filled with generic drugs increased from 67 percent to 78 percent nationwide (and from 63 percent to 73 percent in Part D).

- New brand-name drugs (which tend to be more expensive than older brand-name therapies) were introduced at a slower rate than in the late 1990s.

Spending per beneficiary in Part D has been lower than CBO projected in part because of those developments affecting nationwide drug spending.

In addition to spending per beneficiary, enrollment in Part D has been smaller than CBO initially projected—by about 12 percent in 2012. CBO initially projected the share of eligible people who would enroll in Part D on the basis of enrollment in similar government health care programs—in particular, Part B of Medicare, which is a voluntary program that primarily covers physicians’ and outpatient services for the same population that is eligible for Part D. CBO adjusted that share downward slightly to account for potential enrollees who would have prescription drug coverage through another source, among other factors. But the share of Medicare beneficiaries enrolling in Part D has been substantially lower. One contributing factor is probably that beneficiaries need to make an active effort to enroll in Part D—unlike Part B, in which beneficiaries are usually enrolled by default and must take steps to opt out.

Taken together, the unexpected slowdown in national drug spending per person and smaller-than-expected enrollment in Part D can account for nearly all of the difference between CBO’s original estimate and actual Part D spending. CBO’s original estimate incorporated an expectation that elements of the program’s design that were intended to foster price competition between private plans would help to limit costs per beneficiary. Because other factors have affected costs per beneficiary, determining whether the competitive design of the program has been more or less effective than CBO originally anticipated is not feasible.

### How Has Competition Between Plan Sponsors Affected Part D Spending?

Medicare Part D was designed to foster competition between plan sponsors to constrain drug spending. In assessing the impact of competition, CBO found that a larger number of plan sponsors in a region was associated with lower bids, on average, for the group of plans analyzed.

Each summer, every Part D plan submits a bid that reflects the total amount it would be willing to accept to offer Part D coverage for a Medicare beneficiary of average health for the following year. Once the bids from all plans have been submitted, the government determines the amount it will pay toward the benefit for the average beneficiary. The premium for each plan depends on the difference between a plan’s bid and the government’s payment. Plans with lower costs can submit lower bids and thus offer lower premiums and attract more beneficiaries. Other features of a plan, such as its cost-sharing provisions and the specific drugs it covers, also influence a plan’s attractiveness to potential enrollees.

CBO analyzed bids for “basic stand-alone” Part D plans between 2006 and 2010 and found that plans in regions with more plan sponsors tended to have lower bids and premiums than those in regions with fewer sponsors. (Basic stand-alone Part D plans, which accounted for about half of total Part D enrollment over that period, offer a standard level of prescription drug coverage; CBO excluded from its analysis of plan bids stand-alone plans that offer more generous drug benefits, employment-based plans, and plans that combine drug coverage with coverage for other medical benefits, such as hospitalization and physicians’ services.) Between 2006 and 2007, an average of 6 new plan sponsors joined the market in each of the 34 Part D regions that together cover the United States, contributing to lower bids and lower government spending. However, between 2007 and 2010, the average total number of plan sponsors per region fell by 4 (from 22 to 18), because more sponsors exited the market or merged with other sponsors than entered the market; that decrease in competition is associated with higher bids and higher government spending.

As Part D is currently structured, two features of the program could be changed to encourage plan sponsors to submit lower bids for their plans. First, in the component of Part D that serves low-income beneficiaries, the
government usually pays the full amount of a plan’s bid up to a threshold, regardless of whether other plans bid lower. Second, low-income beneficiaries enrolled in plans whose bid rises above the threshold are automatically reassigned in equal proportions to plans with bids below the threshold (unless a beneficiary has actively signed up for a particular plan). Both of those features encourage plans to set their bids close to (though below) the threshold.

**Has Growth in Payments to Part D Plans Been in Line With Growth in Drug Spending?**

The payments to plans by the government and beneficiaries for the basic Part D benefit increased more rapidly between 2007 and 2010 than did spending for drugs by those plans. Specifically, the payments to stand-alone plans for the basic benefit grew by 3.3 percent per year per beneficiary, on average, whereas plans’ spending per beneficiary on drugs for the basic benefit grew by an average of 2.8 percent per year.

The difference between those growth rates represents an increase in the sum of plans’ administrative costs and profits over the 2007–2010 period. Drawing firm conclusions about the cause of that increase is difficult, in part because of the short time frame of the analysis and a lack of information about whether the initial amounts of administrative costs and profits were unusually low. Nonetheless, some increase in the sum of administrative costs and profits could be explained by the reduction in the number of plan sponsors between 2007 and 2010.

**How Do Prices for Drugs Differ Between Part D and Medicaid?**

For the drug classes representing the great majority of drug spending by Part D beneficiaries, CBO found that Medicaid’s average price for drugs was between 27 percent and 38 percent lower than Part D’s average price in 2010 after controlling for differences in health conditions between beneficiaries of the programs. (Prices are measured net of rebates.) CBO expects that the difference in average prices will narrow over time as drug manufacturers respond to new rules that increased Medicaid’s rebates beginning in 2010 but that Medicaid’s average price will remain at least 20 percent to 30 percent lower than Part D’s average price after controlling for differences in health conditions.

The difference in average drug prices between Part D and Medicaid in 2010 occurred primarily because Medicaid’s statutory rebates on brand-name drugs were generally much larger than the rebates on those drugs negotiated by plan sponsors in Part D. Rates of generic drug use were similar in the two programs, so the higher prices paid by Part D for brand-name drugs were not offset by significantly greater use of generic drugs. However, the higher prices for given brand-name drugs were offset in part by greater use in Part D of lower-priced drugs within therapeutic classes (groups of drugs that are intended to treat common sets of medical conditions and that typically have similar modes of action). If the different patterns of use within therapeutic classes stemmed entirely from differences in the structure of the programs, then the lower end of those ranges—27 percent in 2010 and at least 20 percent in the future—reflects the relative effectiveness of those program structures in containing drug prices. If, instead, the different patterns of use within therapeutic classes stemmed entirely from differences in health conditions between beneficiaries of the programs, then the higher end of those ranges—38 percent in 2010 and at least 30 percent in the future—reflects the relative effectiveness of those program structures in containing drug prices.

Some policymakers have proposed applying Medicaid’s statutory rebates to drug purchases made by Part D beneficiaries who receive low-income subsidies (while retaining the existing structure of Part D in other respects). CBO expects that adopting such a policy would lower the average cost of brand-name drugs in Part D and thus reduce the federal government’s costs over the first decade after the policy was adopted. But a substantial portion of those savings would probably erode over time because drug manufacturers would counter the larger rebates by raising the prices for new brand-name drugs. In addition, that policy would reduce the incentive for firms to develop new drugs.
The Federal Budgetary Cost of Medicare Part D

In 2003, the Congressional Budget Office (CBO) projected that net federal spending for the Medicare Part D program would be $99 billion in fiscal year 2013; actual spending was $50 billion, or nearly 50 percent less than anticipated. Over the 2006–2013 period covered by CBO’s original cost estimate, net federal spending for Part D was projected to be $550 billion; actual spending was $353 billion, or 36 percent less.

This chapter examines the two main factors that primarily account for the lower-than-expected costs. First, the slowdown in nationwide drug spending has been faster than anticipated. CBO estimated in 2003 that the rate of growth in drug spending per person for the nation as a whole would decline gradually toward its average of previous decades but would remain above that average for most of the 10-year projection period (through 2013), consistent with the views of many health care analysts at the time. However, the growth rate of national drug spending per person dropped below its long-term average even before the Part D program was implemented, and the rate has remained low. Because of that lower growth rate, drug spending nationwide in 2012 was about 40 percent less than had been expected by analysts at the Centers for Medicare & Medicaid Services (CMS) in 2003. That difference explains a large share of the amount by which CBO overestimated Part D drug spending for 2012.

Second, participation in Part D has been lower than originally projected. Although CBO estimated that the share of Medicare enrollees who would participate in Part D would be about 7 percent lower than enrollment in Medicare Part B—which turned out to be 92 percent of the total Medicare population in 2012—the actual share of Medicare enrollees in Part D was 21 percent lower, or only 73 percent in 2012. Part B and Part D are similar in several respects, but eligible Medicare beneficiaries are not automatically enrolled in Part D, as they usually are in Part B; instead, they must actively sign up for drug coverage. That requirement may have held down Part D enrollment more than CBO anticipated. In addition, enrollees in Part D are required to choose among various drug plans, whereas enrollees in Part B are not required to make any further choices when enrolling; that difference also may have held down Part D enrollment in a way that CBO did not anticipate. Yet another factor that may have

1. Changes made to the Part D program since its inception have increased federal spending compared with spending under the program’s original design; without those changes, CBO estimates, federal spending in 2013 would have been a few percent lower. Both actual and estimated costs are net of premiums and payments from states to the federal government (often referred to as “clawback payments”) that relate to the shift of beneficiaries from the Medicaid drug program to the Part D program. See Congressional Budget Office, A Detailed Description of CBO’s Cost Estimate for the Medicare Prescription Drug Benefit (July 2004), www.cbo.gov/publication/15841.

2. For another analysis of why the costs for Part D were lower than originally projected, see Jack Hoadley, Medicare Part D Spending Trends: Understanding Key Drivers and the Role of Competition, Medicare Policy Issue Brief (Henry J. Kaiser Family Foundation, May 2012), http://tinyurl.com/nfrhtz4 (PDF, 1.1 MB).

3. See, for example, Stephen Heffler and others, “Health Spending Projections for 2002–2012,” Health Affairs (February 7, 2003), http://dx.doi.org/10.1377/hlthaff.w3.54.

4. CBO cites 2012 figures for two reasons. First, 2012 was the latest year for which projections of nationwide drug spending were available from CMS when CBO projected federal spending under the Medicare Modernization Act in 2003. Second, 2012 is the latest year for which data on actual nationwide drug spending, as reported by CMS in the national health expenditure accounts, are available.
Figure 1-1.
Annual Growth Rates of Drug Spending per Person, 1990 to 2011

![Graph showing annual growth rates of drug spending per person from 1990 to 2011.](image)

Source: Congressional Budget Office based on the historical national health expenditure accounts and Part D claims and rebate data obtained from the Centers for Medicare & Medicaid Services.

Note: Both nationwide and Part D drug spending are net of rebates. The growth rate of Part D spending in 2007 relative to 2006 is not included because many enrollees did not have coverage for the full year in 2006.

a. The Affordable Care Act (ACA) significantly reduced the prices the federal government pays for prescription drugs under Medicaid beginning in 2010. Medicaid accounted for about 8 percent of total spending in the retail pharmacy market in 2010. Nationwide, drug spending per person fell by 0.4 percent in 2010; without the ACA’s reduction in Medicaid’s payment rates, the growth rate per person would have been higher by about 0.5 percentage points, yielding growth of drug spending per person of 0.1 percent.

 Held down Part D enrollment is that Part D covers a smaller share of total medical costs than Part B, on average, and so is less valuable to potential beneficiaries. Partly offsetting its overestimate of the rate of participation in Part D, CBO underestimated the total number of enrollees in Medicare. All told, actual enrollment in Part D in 2012 was about 12 percent lower than CBO expected. That difference in enrollment probably accounts for less than a 12 percent difference in the program’s estimated costs, however, because people who have low drug spending are less likely to enroll.

Taken together, the faster-than-expected slowdown in national drug spending per person and the smaller-than-expected enrollment in Part D account for nearly all of the difference between CBO’s initial projection and actual Part D spending. CBO’s original projection reflected the agency’s judgment that elements of the program’s design that were intended to foster price competition between private plans would help to limit the costs of Part D, yielding lower costs per enrollee than would be expected for a similar population under a typical employment-based drug plan offered at that time. However, determining whether the actual effects of competition have been larger or smaller than those incorporated in the original estimate is not feasible because many other factors have also affected Part D costs.

Prescription Drug Spending per Person Nationwide and in Medicare Part D

Between 2007 and 2010, per capita drug spending nationwide (reflecting both the net price of drugs and the quantity used) increased by about 2 percent per year, on average. That rate is much lower than the average growth rate of such spending—about 13 percent per year—between 1999 and 2003, the five years before enactment of the Medicare Modernization Act (MMA), the law that created Medicare Part D (see Figure 1-1). The national slowdown in per capita drug spending can largely be attributed to a slowdown in the growth of average prices for drugs, which rose by 9 percent per year nationwide.
between 1999 and 2003, CBO estimates, but increased much more slowly between 2007 and 2010.\(^5\)

Although health care analysts expected a slowdown in per capita spending nationwide because of ongoing changes in the prescription drug market that were independent of the implementation of Part D, spending slowed much more dramatically than most analysts had anticipated. For example, in 2004, CMS projected that drug spending for the nation as a whole would total just over $3 trillion for the 2006–2013 period. By 2006, after enactment of the MMA but before its implementation could have had significant effects, that figure had been revised downward substantially, to $2.3 trillion; the most recent data and projections by CMS suggest that actual spending over the period will be about $2 trillion, or one-third less than CMS had projected around the time that the legislation was enacted.\(^6\) By 2012, drug spending nationwide was about 40 percent less than what CMS had projected for that year in 2003, before enactment of the MMA. Because CBO’s expectations for national drug spending were similar to CMS’s projections, CBO’s original cost estimate for Part D also reflected much higher amounts of drug spending than have occurred.

Two developments in particular contributed to the slow rate of growth in national drug spending after 2003:

- **Patent Expiration and Generic Entry.** Many existing brand-name drugs lost their patent protection, which led to an increase in the introduction and use of less expensive generic substitutes.

- **Slow Entry of New Brand-Name Drugs.** The introduction of new brand-name drugs, which tend to be more expensive than older brand-name therapies, slowed relative to its pace in the late 1990s. Those developments held down growth in spending per person in Part D as well as nationwide. Between 2007 and 2010, per capita spending on prescription drugs both nationwide and in Part D grew by about 2 percent per year, on average (see Figure 1-1).\(^7\)

To assess the importance of those developments for Part D spending, CBO used data on the claims of Part D beneficiaries and on rebates received between 2007 and 2010 to calculate the changes in the prices (net of rebates) for, and the use of, brand-name and generic drugs. (Comparable data are not readily available for drug spending nationwide.) Between 2007 and 2010, the average price of a 30-day supply of *brand-name* drugs used by Part D beneficiaries rose from $109 to $141, and the average price of a 30-day supply of *generic* drugs fell from $22 to $21 (see Figure 1-2).\(^8\) The expiration of patents on existing brand-name drugs, combined with a slow rate of entry of new brand-name drugs into the market, caused the use of generic drugs as a share of total drugs taken by Part D beneficiaries to increase from 63 percent in 2007 to 73 percent by 2010. Taking those factors together, the average price of a 30-day supply of drugs for Part D beneficiaries fell by less than $1, equaling approximately $54 in both 2007 and 2010. In percentage terms, that decline in the average price was 0.5 percent per year between 2007 and 2010 (see Table 1-1). Over that same period, the average quantity of drugs consumed by Part D beneficiaries rose 2.6 percent per year, resulting in an average annual increase of 2.1 percent in drug spending per person.

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5. CBO estimated nationwide price changes using the average price for a prescription (excluding those filled by mail order). That approach did not account for any changes in the sizes of prescriptions or in the amounts of rebates over that period. To the extent that prescription sizes increased or rebates grew as a share of drug spending, the contribution of price growth to spending per person would be somewhat overstated. Average drug prices can increase either because manufacturers raise their prices or because the mix of drugs used shifts toward higher-priced drugs.


7. Differences between the growth rates of per capita drug spending in Part D and nationwide occur in part because of different patterns of drug use between the Medicare population and the U.S. population as a whole. For example, cardiovascular drugs accounted for four of the top five drug classes used by Part D beneficiaries but only two of the top five classes used nationwide. Seven cardiovascular drugs lost patent protection between 2006 and 2010; that loss contributed to the observed difference between the spending patterns of Part D beneficiaries and those of the overall population. See IMS Institute for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2011* (April 2012), [http://tinyurl.com/q977mec](http://tinyurl.com/q977mec) (PDF, 1.5 MB), and *Medicare Part D at Age Five: What Has Happened to Seniors’ Prescription Drug Prices?* (July 2011), [http://tinyurl.com/pr5an5p](http://tinyurl.com/pr5an5p) (PDF, 254 KB).

8. Prescriptions commonly provide a 30-day supply, with refills for drugs taken over a longer period.
Figure 1-2.
Changes in the Use of and Prices for Brand-Name and Generic Drugs in Medicare Part D Between 2007 and 2010

<table>
<thead>
<tr>
<th>Percentage of Drug Use</th>
<th>Dollars per 30-Day Supply</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>2010</td>
</tr>
<tr>
<td>63%</td>
<td>73%</td>
</tr>
<tr>
<td>Generic Drugs</td>
<td>$22</td>
</tr>
<tr>
<td>Brand-Name Drugs</td>
<td>$109</td>
</tr>
<tr>
<td>Average in Both Years</td>
<td>$54</td>
</tr>
<tr>
<td>37%</td>
<td>27%</td>
</tr>
</tbody>
</table>

Source: Congressional Budget Office based on Medicare Part D claims data and summary data on total manufacturer rebates paid to Part D plans (obtained from the Centers for Medicare & Medicaid Services), as well as Red Book data (available from Truven Health Analytics) to determine whether a drug was brand-name or generic.

Note: Prices for brand-name drugs are net of rebates.

Patent Expiration and Generic Entry
From 2007 to 2010, many brand-name drugs lost their patent protection and faced new competition from generic substitutes. Those developments contributed to an increase in the share of prescriptions nationwide for which a generic version is available from 74 percent in 2007 to 84 percent in 2010; within Part D, the increase was similar. Over the same period, the use of generic drugs nationwide as a share of all drugs rose from 67 percent to 78 percent—an increase roughly equivalent to that observed in the Part D market.

The increased use of generic drugs stems from two types of substitution, both of which reduced the average price of drugs used. First, generic drugs were substituted for their brand-name counterparts that lost patent protection. Such substitution decisions are guided by state laws and often made by the pharmacist or the beneficiary (a decision based partly on the drug’s relative copayment, or the amount the beneficiary pays to fill the prescription) and typically do not require permission from the prescribing physician. Between 2007 and 2010, more than 90 percent of prescriptions were filled with a generic alternative (when one was available) within 12 months of patent expiration; that share was larger than was observed in 2002, for example, when 72 percent of prescriptions were filled with an available generic alternative within 12 months of patent expiration.9

Second, physicians shifted away from treatments with only brand-name drugs to treatments with different active ingredients that are therapeutically similar (in other words, that use similar means for controlling a symptom or condition and have comparable effects) but that exist in generic form. For example, many brand-name “statin” drugs were available to treat high cholesterol in that period, with some available in generic form and others not. Only the prescribing physician, not the beneficiary or pharmacist, can determine whether such substitutions to therapeutically similar drugs are appropriate. Although both types of substitution appear to be occurring, CBO has not quantified the contribution of each type to the total shift to generic drugs.10

Spending data available for Part D beneficiaries illustrate the extent to which generic entry can reduce the average retail price of drugs (see Table 1-2). (The retail price is the price paid by Part D plans to retail pharmacies for drugs purchased by beneficiaries and is higher than the net price, which includes the rebates that Part D plan sponsors negotiate with manufacturers.) For brand-name drugs that remained protected by patents, the average


10. Although the market share of new generic drugs (as measured by quantity used) increased by 12 percentage points nationwide from 2007 to 2010, the market share of the corresponding brand-name drugs that lost patent protection between 2006 and 2010 declined by only 8 percentage points. That difference probably arose from the substitution of drugs that are therapeutically similar and from other factors that increased the market share of drugs losing patent protection relative to the market share of other drugs that did not recently lose patent protection.
Table 1-1.
Average Drug Prices, Quantities, and Spending Under Part D, 2007 to 2010

<table>
<thead>
<tr>
<th></th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>Average Increase per Year (Percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price of a 30-Day Supply* (Dollars)</td>
<td>54.3</td>
<td>53.8</td>
<td>53.7</td>
<td>53.5</td>
<td>-0.5</td>
</tr>
<tr>
<td>Quantity of Drugs Consumed (Number of 30-day supplies per person)</td>
<td>42.5</td>
<td>44.1</td>
<td>45.2</td>
<td>45.9</td>
<td>2.6</td>
</tr>
<tr>
<td>Drug Spending* (Dollars per person)</td>
<td>2,304</td>
<td>2,376</td>
<td>2,428</td>
<td>2,453</td>
<td>2.1</td>
</tr>
</tbody>
</table>

**Memorandum:**
- Rebates as a Share of Total Retail Spending (Percent): 9.7, 10.4, 11.1, 11.3, 5.3
- Generic Drugs as a Share of the Number of 30-Day Supplies (Percent): 63, 68, 70, 73, 5.0

Source: Congressional Budget Office based on Medicare Part D claims data and summary data on total manufacturer rebates paid to Part D plans (obtained from the Centers for Medicare & Medicaid Services), as well as Red Book data (available from Truven Health Analytics) to determine whether a drug was brand-name or generic.

a. The price of a 30-day supply represents the average price of brand-name and generic drugs, net of rebates.
b. Spending per person equals the price of a 30-day supply multiplied by the number of 30-day supplies per person.

d. The price of a 30-day supply represents the average price of brand-name and generic drugs, net of rebates.

**Slow Entry of New Brand-Name Drugs**
The Food and Drug Administration approved about 40 percent fewer new brand-name drugs each year, on average, between 2007 and 2010 than in the late 1990s. Between 1996 and 1999, 39 brand-name drugs representing new chemical entities were approved each year, on average; between 2007 and 2010, that figure was just 22, on average (although it jumped up to 39 in 2012 before receding to 27 in 2013).14

11. The weights represent the number of days supplied for brand-name and generic drugs.

12. That calculation reflects simplifying assumptions that the market share of drugs (as measured by quantity used) would have been unaffected by that difference in price and that the prices of drugs that recently lost patent protection would have risen at the same rate as prices of patent-protected brand-name drugs (8.5 percent annually, on average) rather than declining by 19.8 percent annually, on average. The 1.2 percent increase in the average retail price of drugs shown in Table 1-2 differs from the 0.5 percent decrease in the average price of a 30-day supply of drugs shown in Table 1-1 because Table 1-2 does not include the effects of rebates or the substitution of drugs that are therapeutically similar, both of which are accounted for in Table 1-1.


Table 1-2.

Changes in Average Retail Drug Prices in Part D, 2007 to 2010

<table>
<thead>
<tr>
<th>Drug Product Group</th>
<th>2007 to 2008</th>
<th>2008 to 2009</th>
<th>2009 to 2010</th>
<th>Average Change per Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent-Protected Brand-Name Drugs</td>
<td>7.8</td>
<td>9.0</td>
<td>8.7</td>
<td>8.5</td>
</tr>
<tr>
<td>Recently Off-Patent Brand-Name Drugs and Generic Counterparts</td>
<td>-19.7</td>
<td>-21.5</td>
<td>-18.0</td>
<td>-19.8</td>
</tr>
<tr>
<td>Older Off-Patent Brand-Name Drugs and Generic Counterparts</td>
<td>-3.5</td>
<td>-2.2</td>
<td>-4.7</td>
<td>-3.4</td>
</tr>
<tr>
<td>All Drugs</td>
<td>0.4</td>
<td>2.0</td>
<td>1.2</td>
<td>1.2</td>
</tr>
</tbody>
</table>

Source: Congressional Budget Office based on Medicare Part D claims data (obtained from the Centers for Medicare & Medicaid Services) and Red Book data (available from Truven Health Analytics) to determine whether a drug was brand-name or generic.

Note: The change in prices is based on the set of drugs purchased in the initial year of the time period analyzed. The average price for a drug product group is calculated by weighting the price of a particular product in the group by the number of days for which that product was supplied. “Drug products” combine brand-name products with their generic counterparts having the same chemical entity, dosage form, and strength. (Over time, as new generic drugs are substituted for their higher-priced brand-name counterparts, the average price of a drug product generally declines.)

- The drugs included in each product group change somewhat over time. That change can occur, for example, when a brand-name drug loses its patent protection and moves to recently off-patent status.
- Recently off-patent brand-name drugs include drugs that first experienced competition from generic drugs in the year prior to the period analyzed through the end of the period analyzed. For example, for the 2007–2008 period, that category includes drugs that first experienced generic competition between 2006 and 2008, and for the 2009–2010 period, it includes drugs that first experienced generic competition between 2006 and 2008, and for the 2009–2010 period, it includes drugs that first experienced generic competition between 2008 and 2010.

Certain new drugs tend to increase in price and quantity sold as they become more widely recognized; thus, total spending climbs rapidly for new drugs that become top sellers over the first several years they are on the market.\(^\text{15}\) The introduction of many new drugs in the late 1990s contributed to higher rates of growth in drug spending in the early 2000s. By contrast, fewer new drugs were launched in the United States per year over the 2004–2010 period (especially in 2007 and 2008), which contributed to declining spending on new drugs from 2007 to 2010.\(^\text{16}\) Indeed, all of the top 20 drugs in 2010, as measured by sales, had been introduced by 2004. In particular, a smaller number of brand-name drugs reached “blockbuster” status (more than $1 billion in annual sales nationwide) between 2007 and 2010 than earlier in the decade. Although the total number of blockbuster drugs increased each year between 1997 and 2006, it declined between 2007 and 2010 because of patent expirations, causing the average prices for a number of drugs to fall.\(^\text{17}\) The emergence of fewer blockbuster drugs may also have constrained growth in the quantity of drugs consumed; that quantity can increase if new blockbuster drugs represent previously unavailable treatments or allow beneficiaries to substitute a drug therapy for a medical procedure.\(^\text{18}\)

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The smaller number of new blockbuster drugs since 2007 stems in part from a decrease in the rate of introduction of drugs that treat diseases or conditions affecting many people.19 New brand-name drugs are categorized in one of three ways: as a novel treatment (the first product with approval from the Food and Drug Administration to use a certain mechanism to treat a particular disease), as a new drug that extends an existing treatment mechanism, or as an orphan drug (one that treats rare diseases affecting fewer than 200,000 people). The number of novel treatments per year fell from an average of 14 in 2002 and 2003 to an average of 7 between 2007 and 2010. In contrast, the introduction of drugs that extended existing treatment mechanisms rose slightly, from an average of 7 to an average of 9 per year, between the 2002–2003 and 2007–2010 periods, and the number of new brand-name drugs classified as orphans increased from an average of 4 to an average of 7 per year over those two time periods.20 The reduced introduction of novel treatments and the relatively constant introduction of drugs that extended existing treatment mechanisms, combined with patent expirations, contributed to a decline in the share of prescriptions written for brand-name drugs between 2006 and 2010. Although the slow rate of introduction of new brand-name drugs through 2010, especially drugs reaching blockbuster status, has held down growth in drug spending in recent years, it has also meant that patients have not benefited from new treatments at the same rates as before.

**Enrollment in Medicare Part D**

Spending in Medicare Part D has also turned out to be lower than CBO originally estimated because enrollment in the program has been lower than the agency expected. CBO based its original estimates largely on historical rates of participation in Medicare Part B, which covers mainly physicians’ and outpatient services.21 Parts B and D of Medicare have several similarities: Both are voluntary programs, provide premium subsidies of about 75 percent, and impose significant penalties for late enrollment. Although 94 percent of Medicare beneficiaries in the early 2000s were enrolled in Part B, CBO estimated that participation in Part D would be slightly lower—about 87 percent—because some Part B enrollees (in particular, federal retirees and some active private-sector workers) would have drug coverage through other sources and therefore would not sign up for Part D. (Retirees from private firms who receive drug coverage through their former employer that is subsidized by Medicare Part D were included in CBO’s estimate of Part D participation and are likewise included in counts of Part D enrollees.)

Actual enrollment in Part D in 2012 was 12 percent lower than CBO originally estimated—but because beneficiaries with low drug spending are less likely to enroll in Part D, that difference in enrollment probably accounts for less than a 12 percent difference in the program’s costs.22 Although CBO underestimated the total number of enrollees in Medicare, it overestimated the share of those enrollees who would participate in Part D. In 2012, 73 percent of the total Medicare population enrolled in Part D, which is substantially lower than Part B enrollment (92 percent of Medicare beneficiaries in that year) and also lower than the 87 percent of Medicare beneficiaries CBO originally estimated would enroll in Part D.

One likely reason for the difference in enrollment between Part B and Part D is the default enrollment procedures. Such procedures have been shown in recent studies to significantly affect enrollment rates in various sorts of activities.23 Most people enroll in Social Security by the time they turn 65; at that point, they are automatically enrolled in Medicare Part A and must take active

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22. See Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (March 2012), p. 345, http://tinyurl.com/octakc3 (PDF, 9 MB); that report suggests that 10 percent of Medicare enrollees lack drug coverage or have coverage that is less extensive than that available through Part D and that those enrollees incur drug spending that is below average.

steps to avoid being enrolled in Part B.24 By contrast, they are not generally enrolled by default in Part D. That difference may have mattered more than CBO had anticipated.

Another possible reason for lower enrollment in Part D than in Part B is the complexity of the choices involved in signing up for the coverage. When deciding whether to enroll in Part D, Medicare beneficiaries must choose among the various drug plans available to them. For Part B, in contrast, beneficiaries face the much simpler choice of whether or not to enroll in the program. Some researchers have found that giving people an abundance of choices increases the probability that they will make no choice at all, although other researchers have reached the opposite conclusion; CBO’s original estimate did not account for a possible effect of that sort.25

24. Medicare beneficiaries generally cannot avoid enrolling in Part A.

A third possible reason for lower enrollment in Part D than in Part B is that some Medicare beneficiaries may not value Part D coverage as highly as they value coverage from Part B, which covers a larger share of total medical costs, on average. Again, that factor may have mattered more than CBO had expected.

Many elements of the Medicare Part D program were designed to foster competition between plan sponsors. When potential enrollees choose between drug plans, they consider various characteristics of those plans, including premiums, the drugs that are covered, the ease of using a plan’s network of pharmacies, and other features. Because of the competitive design of Part D, plan sponsors have ongoing incentives to provide a combination of characteristics that attract potential enrollees while keeping premiums low. To keep premiums low, plan sponsors need to hold down costs (see Appendix A for an illustration of how plans’ bids are used to determine enrollees’ premiums). In the Part D program, plans’ premiums and enrollees’ choices of plans help determine the costs borne by the federal government, because the government’s payments for the basic benefit are based largely on the enrollment-weighted average of plans’ bids.

This chapter examines the ways in which competition between plan sponsors reduces the cost of the Part D program. Using data for the subset of Part D beneficiaries in basic stand-alone plans from the first few years of the Part D program, the Congressional Budget Office found that plans’ bids were lower when a larger number of plan sponsors competed in a region. This analysis excludes bids from Medicare Advantage drug plans: Because those plans are offered only in conjunction with coverage for physicians’ and hospital services, they present a different set of choices for beneficiaries. (See Box 2-1 for more details about the basic drug benefit.) Between 2006 and 2007, the average number of competing plan sponsors per region increased and bids fell. CBO’s analysis implies that bids fell partly because of increased competition and partly for other reasons, including plans’ overestimating costs in the first year of the program, when they had no historical experience on which to draw. From 2007 to 2010, by contrast, the average number of competitors per region fell and bids increased somewhat more quickly, on average, than drug spending. Bids increased more in areas with a larger reduction in the number of competitors, which suggests that the sum of profits and administrative costs probably rose more for firms in those areas than for firms in other areas.

Certain rules of the Part D program reduce the incentives for plans to offer lower bids and premiums. Primarily, those rules govern beneficiaries who receive low-income subsidies under Part D, which are substantially greater than the subsidies that other beneficiaries receive. (In general, recipients must have both low income and few assets or resources to qualify for Part D’s low-income subsidies, but for simplicity those recipients are referred to as low-income beneficiaries throughout this report.) CBO’s analysis suggests that changing the rules to strengthen the incentives for plans to lower their bids could reduce the cost of the program, although those changes could have disadvantages as well.

1. For more information on drug spending and on the structure of Part D, see Congressional Budget Office, Spending Patterns for Prescription Drugs Under Medicare Part D (December 2011), www.cbo.gov/publication/42692.

2. Enrollees in stand-alone plans represented about 65 percent of Part D enrollment during the 2007–2010 period covered by this analysis. Almost 80 percent of those enrollees joined a basic plan, with the remaining 20 percent in enhanced plans. Excluding enrollees who received low-income subsidies, about 60 percent of enrollees in stand-alone plans selected a basic plan.

3. Other researchers have analyzed the effects of competition between Medicare Advantage plans and found that bids tended to be lower when a larger number of plan sponsors were present. See Zirui Song, Mary Beth Landrum, and Michael E. Chernew, “Competitive Bidding in Medicare Advantage: Who Benefits From Competition,” American Journal of Managed Care, vol. 18, no. 9 (September 2012), pp. 546—552, www.ncbi.nlm.nih.gov/pmc/articles/PMC3519284.
Two broad categories of plans participate in Medicare Part D: stand-alone prescription drug plans, which enroll beneficiaries who receive their other Medicare coverage through the traditional fee-for-service program, and Medicare Advantage prescription drug plans. (A small share of beneficiaries are enrolled in Part D plans offered through their former employer or union; the Part D program also provides subsidies to retirees who are enrolled in a private employer’s or union’s plan rather than a Part D plan.) Under Medicare Advantage, enrollees choose among available private health plans for their nondrug Medicare benefits; those enrollees must obtain both prescription drug coverage and nondrug coverage from the same plan, which causes the plans’ sponsors to compete for beneficiaries on the basis of the cost and design of their entire insurance product and not just Part D coverage.

For stand-alone and Medicare Advantage plans in 2014, the basic drug benefit has the following standard features:

- No coverage for the first $310 of drug spending (the deductible);

- Coverage for 75 percent of spending between the deductible and an initial coverage limit of $2,850;

- Limited coverage for generic and brand-name drugs when spending is between the initial coverage limit and a catastrophic limit on out-of-pocket costs of $4,550 (a range of spending sometimes referred to as the coverage gap or “doughnut hole”); and

- Coverage for 95 percent of spending above the catastrophic limit.

Basic plans may strictly follow that benefit structure, or they may adjust certain cost-sharing features while covering the same share of drug spending for beneficiaries, on average, as the benefit outlined above—in other words, they may offer a benefit that is “actuarially equivalent,” subject to some constraints. In addition to the basic benefit, some plans offer supplemental coverage for which beneficiaries pay an additional premium. Those plans are sometimes referred to as enhanced plans. Benefits offered by enhanced plans may include additional coverage in the coverage gap, lower copayments or coinsurance, or a lower deductible. Over the 2007–2010 period, almost 80 percent of beneficiaries in stand-alone plans were enrolled in a basic plan, with the remaining share enrolled in enhanced plans. Of the group of beneficiaries in stand-alone plans who were not receiving low-income subsidies, 60 percent were in basic plans and the rest were in enhanced plans.

Under current law, the coverage gap will be phased out by 2020. Since 2011, drug manufacturers have been required to offer a discount of 50 percent on purchases of brand-name drugs in the coverage gap for all beneficiaries who do not have sufficiently low income to qualify for cost-sharing subsidies. In addition, Part D plans will gradually cover a larger share of spending for those beneficiaries each year; by 2020, beneficiaries will be responsible for 25 percent of the cost for both brand-name and generic drugs between the deductible and the catastrophic limit. (Beneficiaries receiving low-income subsidies do not face a coverage gap because their cost-sharing subsidies cover most of their out-of-pocket costs.)

Payments by Part D to each plan reflect the plan’s estimated and actual costs, including administrative costs and profits, of providing the basic Part D
Box 2-1. The Structure of the Basic Benefit and Federal Payments for Medicare Part D

The Federal Government’s Payments to Part D Plans, 2010

<table>
<thead>
<tr>
<th>Billions of Dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reinsurance</td>
</tr>
<tr>
<td>11.2</td>
</tr>
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</table>

Source: Congressional Budget Office based on data from the Centers for Medicare & Medicaid Services (CMS).

Note: Plan payments are on an incurred basis and exclude risk corridor payments, which are payments made to (or from) the federal government when plans overestimate (or underestimate) their spending relative to actual spending beyond a threshold amount. On net, plans made $0.9 billion in risk corridor payments to CMS in 2010.

benefit to an average Medicare beneficiary. Specifically, federal payments to plans for the basic benefit take two forms. First, reinsurance payments cover 80 percent of incurred drug costs above the catastrophic limit. Second, direct subsidy payments are based on each plan’s bid, which reflects its estimated cost of providing the basic benefit excluding expected reinsurance payments. (For a visual presentation of the calculation of payments to plans by different sources, see Appendix A on page 37.) Together, those two federal payments are designed to equal about 75 percent of the average cost of the basic benefit. In 2010, direct subsidy payments totaled $19.7 billion, and reinsurance payments totaled $11.2 billion (see the figure).

The federal government provides additional subsidies for beneficiaries who have income and assets below a certain threshold, many of whom are eligible for both Medicare and Medicaid. People who are eligible for both programs receive a full subsidy to cover their premium—up to a certain limit that is set regionally—plus subsidies to cover most of their deductibles and copayments. Other Medicare beneficiaries with low income and few assets also qualify for additional federal assistance, which ranges from partial to full coverage of their premiums, deductibles, and copayments. In 2010, the additional premium subsidies for low-income beneficiaries totaled $3.3 billion, and subsidies for deductibles and copayments for low-income beneficiaries totaled $17.8 billion.

Beneficiaries who do not qualify for low-income subsidies generally pay about 25 percent of the average cost of the basic benefit through their premiums. (Beneficiaries with income that exceeds a certain amount are required to pay more than 25 percent of the average cost of the basic benefit.) In addition, they pay any deductible and copayments associated with their plan. As part of those copayments, beneficiaries directly cover 5 percent of spending in excess of the catastrophic limit, and the federal government covers 80 percent of those costs through the reinsurance payments; the expected cost of the remaining 15 percent is incorporated into plans’ bids.
Beneficiaries’ Choices
The main mechanism through which competition in the Medicare Part D market reduces the program’s costs has two related components.

First, when beneficiaries select a plan, they tend to select less-expensive plans from among those offered, which provides an incentive for plans to submit low bids. Before the start of each year, beneficiaries are presented with a choice of plans and their associated premiums. Each plan must offer at least the basic level of prescription drug coverage, which makes the plans easier to compare. Although the total cost to a beneficiary includes the premium, deductible, and other out-of-pocket expenses, beneficiaries tend to choose plans with lower premiums, which encourages plans to compete on that basis.4

In particular, enrollees tend to choose plans with premiums close to the lower end of the range that is offered. In 2007, the average monthly premium offered across the 34 Part D bidding regions (including both basic and enhanced plans) was about $36. The difference in premiums between the least expensive and most expensive plan exceeded $62 in all regions. (When limited to basic plans only, the difference in premiums between the least expensive and most expensive plan always exceeded $30.) Fifty-five percent of enrollees not receiving a low-income subsidy chose a plan whose premium was within $15 of the least expensive plan in their region, and 75 percent chose a plan whose premium was within $20 of the least expensive plan in their region.5

Second, plans have a significant number of potential new enrollees each year, which encourages competition between plan sponsors. At the end of each year, there is an open-enrollment period for the coming year. In general, plans can change their benefits and premiums only at that time, and most beneficiaries can choose a plan only during those periods or when they are newly eligible for Medicare. (Beneficiaries who receive low-income subsidies can change their plan at any time.) CBO found that between 2007 and 2010, about a quarter of beneficiaries in stand-alone plans joined a new plan each year. In addition, about a third of beneficiaries who joined a new plan each year were new to the program and enrolling in a plan for the first time, while the other two-thirds were switching from other stand-alone plans—which had higher premiums, on average, than the new plan they joined.6

Federal Payments
Federal payments are set to cover about 75 percent of the average cost of the basic drug benefit, and beneficiaries’ premiums cover the remainder. A small part of that 75 percent subsidy on the basic benefit is offset by a surcharge levied on beneficiaries whose income exceeds a certain threshold. The federal government’s payments take several forms:

- Direct subsidy payments are based on the bids of all plans and do not vary depending on an enrollee’s choice of plans: Enrollees who choose a more expensive plan pay a premium that is correspondingly higher, and enrollees who choose a less expensive plan keep the resulting savings. Lower bids by plans, weighted by enrollment, translate into lower payments by the federal government (see Appendix A).

- Reinsurance payments are based on actual drug costs and cover 80 percent of an enrollee’s spending once it exceeds a catastrophic threshold ($4,550 in 2014). The reinsurance payments combined with the direct subsidy payments are designed to cover about 75 percent of the average cost of the basic benefit. Those reinsurance payments greatly limit plans’ costs for enrollees with high drug spending, but they also


5. In 2007, the average premium among plans chosen by enrollees was $27. That number is lower than the average monthly premium offered in the 34 Part D bidding regions ($36) because enrollees tended to choose less expensive plans.

6. Other researchers have also found that beneficiaries who switch plans lower their premiums and out-of-pocket costs. For example, see Jonathan D. Ketcham and others, “Sinking, Swimming, or Learning to Swim in Medicare Part D,” American Economic Review, vol. 102, no. 6 (October 2012), pp. 2639–2673, http://dx.doi.org/10.1257/aer.102.6.2639.
reduce plans’ incentives to control spending for those enrollees.

Subsidies to low-income beneficiaries cover the enrollee’s premium, up to a maximum amount. The maximum premium subsidy, commonly called the low-income benchmark, is determined annually for each Part D region and is designed to provide low-income beneficiaries with a variety of plan choices for which their premium is zero. Low-income beneficiaries who select a plan with a premium above the low-income benchmark pay the difference between the benchmark and the plan’s premium.

Subsidies to low-income beneficiaries also cover most cost-sharing amounts. For all plans, most low-income beneficiaries make small copayments, ranging from about $1 to $3 per prescription for generic drugs and about $4 to $6 per prescription for brand-name drugs in 2014.

Payments to plans are adjusted in ways that are designed to encourage plan sponsors to participate in the program and to address problems that sometimes arise in health insurance markets. For example, the government’s payments to each plan are adjusted for the specific health conditions of the beneficiaries enrolled in that plan (a procedure known as risk adjustment). That mechanism compensates plans that attract a large number of beneficiaries whose medical conditions raise their expected drug costs, and it reduces the incentive for plans to selectively market themselves to beneficiaries who they believe will be healthy and therefore less expensive to insure.

CBO’s analysis of plans’ bids defined those bids as they are specified in the law—that is, a bid equals the amount the plan is willing to accept to provide the basic benefit to a beneficiary of average health minus the amount the plan expects to be paid in the form of reinsurance.

**Competition and Plan Bidding**

The competitive pressure on plans in Medicare Part D is stronger when more plan sponsors compete in a region. Between 2006 and 2007, the number of plan sponsors offering stand-alone plans in the Part D program increased from an average of 16 competitors per region to an average of 22 competitors. Many of the plan sponsors that offered a stand-alone drug plan for the first time in 2007 had offered a drug plan in 2006 as part of a Medicare Advantage plan. In 2008, the number of plan sponsors per region fell to 18, on average, and remained there through 2010. Plan sponsors who exited particular regional markets tended to be those that were purchased by another plan sponsor or had low enrollment; new plan sponsors also joined some markets during each year of the analysis.

After controlling for a variety of other factors, CBO found that between 2007 and 2010, plan sponsors in regions with more competitors submitted lower bids for basic stand-alone plans. Specifically, statistical analyses conducted by CBO under several modeling specifications found that having an additional plan sponsor in a region was correlated with an average reduction in bids of 20 cents to 50 cents per enrollee per month among plans with a premium above the low-income benchmark in the previous year. That reduction represents about half a percent of the average bid for that subset of plans. Conversely, having one fewer plan sponsor in a region was associated with an average increase in bids of 20 cents to 50 cents per enrollee per month among such plans. (The economic theory of auctions and some models of price competition predict that as the number of competitors in a market increases, prices fall by less for each additional competitor. Consistent with that theory, CBO found that adding one plan sponsor in a market with 20 sponsors was associated with bids that were about 10 cents lower than when a sponsor was added to a market with only 15 sponsors.) According to that estimate, if the number of plan sponsors had not fallen between 2007 and 2010, the corresponding reduction in bids would have saved the government between $30 million and $70 million in

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7. Each plan sponsor may offer more than one plan. CBO’s analysis measures competition by the number of plan sponsors rather than plans, because it is plan sponsors that determine the pricing and other characteristics of the plans. In CBO’s view, plan sponsors can generally predict how many competitors they will face in the coming year as they prepare their bids. That view is consistent with the approach used in other analyses; see, for example, Dennis P. Scanlon and others, “Competition in Health Insurance Markets: Limitations of Current Measures for Policy Analysis,” *Medical Care Research and Review*, vol. 63, no. 6 (December 2006), pp. 37S–55S, www.ncbi.nlm.nih.gov/pubmed/17099129.

2010 (or about 0.1 percent of net federal spending on Part D).9

To further lower the government’s costs for Part D by fostering greater competition between plan sponsors, the government could try to develop policies that would increase the average number of sponsors per region. However, it is unclear which policies would have that effect (apart from policies that simply raised total payments to plans, which would increase the government’s costs). Alternatively, the government could adjust policies to make it easier for plans with low bids to attract beneficiaries, which would increase the incentive for plan sponsors to set low bids. For example, the government could send information to beneficiaries about the cost of their plan and other plans offered in their region during the open-enrollment period.10 Or the government could require that all beneficiaries actively reaffirm their choice of plan, select a new plan every few years, or be reassigned to a low-cost plan in their region that covered the drugs they have been taking (not all plans cover all drugs); those sorts of changes in policy would increase the likelihood that beneficiaries would select low-cost plans, although it might also cause some inconvenience to beneficiaries or even lead them to exit the program.

**Program Features That Reduce Incentives to Bid Low**

Even though the Medicare Part D program was generally designed to encourage competition between plan sponsors on the basis of plans’ premiums, certain aspects of the program dampen the incentive to submit lower bids. In particular, the rules for low-income beneficiaries and catastrophic drug coverage, as well as other features of the program that reduce plans’ risks, lessen the incentives for plans to constrain drug spending and keep their bids and premiums low. Those elements of Part D reflect trade-offs made by policymakers to achieve the multiple goals of protecting low-income beneficiaries from financial hardship, encouraging plan sponsors to participate in the Part D market, and holding down the government’s costs.

**Rules for Low-Income Beneficiaries**

Even though the Medicare Part D program was generally designed to encourage competition between plan sponsors on the basis of plans’ premiums, certain aspects of the program dampen the incentive to submit lower bids. In particular, the rules for low-income beneficiaries and catastrophic drug coverage, as well as other features of the program that reduce plans’ risks, lessen the incentives for plans to constrain drug spending and keep their bids and premiums low. Those elements of Part D reflect trade-offs made by policymakers to achieve the multiple goals of protecting low-income beneficiaries from financial hardship, encouraging plan sponsors to participate in the Part D market, and holding down the government’s costs.

**Rules for Low-Income Beneficiaries**

Two aspects of Part D’s rules for low-income beneficiaries—the way in which their premiums are set and the way in which they are assigned to plans—reduce the incentive for plan sponsors to submit low bids.

First, most low-income beneficiaries who select a plan with a premium below the low-income benchmark set by the government pay no premium for Part D coverage; the government pays their premium (as well as some of their cost-sharing amounts). However, if those beneficiaries select a plan with a premium above the benchmark, they are required to pay any difference between the plan’s premium and the benchmark. Accordingly, most low-income beneficiaries have an incentive to select a plan with a premium below the benchmark but have no incentive to select lower-cost plans among the plans that meet that criterion.

Second, the rules for assigning some low-income beneficiaries to plans do not distinguish among plans whose premiums are below the benchmark. Specifically, beneficiaries who are already covered by Medicaid when they become eligible for Medicare are randomly assigned to a Part D plan with a premium below the benchmark if they do not actively choose a plan themselves, and low-income beneficiaries who have been assigned to a plan whose premium subsequently exceeds the benchmark are reassigned randomly to one of the plans with a premium below the benchmark.11 Between 2007 and 2010, 1 million to 2 million low-income beneficiaries a year were automatically reassigned to plans with premiums below the low-income benchmark for their region, and they were assigned evenly across those plans regardless of the extent to which the plans’ premiums were below the benchmarks. Plans with premiums below the benchmarks received an average of 4,000 new beneficiaries each year.

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9. Those estimated savings reflect only changes in the bids of basic plans with a premium above the low-income benchmark in the previous year. (Enrollees in such plans account for about 20 percent of total Part D enrollment between 2007 and 2010.) Reductions in the number of competitors may also be associated with increases in the bids of other types of plans—such as enhanced plans or Medicare Advantage plans—but those changes have not been analyzed here and thus are not included in the estimate.


11. By contrast, low-income beneficiaries who have actively chosen their current plan are not reassigned by CMS if their plan’s premium exceeds the benchmark; instead, they are charged the difference in cost between the benchmark and their plan’s premium.
through that process; in some regions and years, such plans received more than 15,000 new beneficiaries.

For both of those reasons, plans with the lowest premiums do not end up with more beneficiaries than plans with higher premiums that are still below the benchmark—but their lower bids cause them to receive smaller payments. Therefore, if a plan was designed to appeal mainly to low-income beneficiaries or to serve primarily new beneficiaries who were automatically reassigned, that plan’s sponsor would have an incentive to submit a bid for the plan that caused its premium to be just below the benchmark but not any lower. Such strategic planning was made easier because the benchmark in each region rarely fell after 2007 and when it did, fell by only a few dollars from year to year; most benchmarks have risen by a few dollars per year since 2007.12

The share of enrollees in plans with premiums below the benchmark who received the low-income subsidy increased from an average of 70 percent in the first few years of the program to 90 percent by 2009. Because beneficiaries in those plans tended not to be sensitive to an increase in the plans’ premiums and because those plans already offered premiums on the lower end of the range in those regions, the plans could raise their premiums toward the benchmarks without losing many enrollees. Over the 2007–2010 period, plans with a premium below the benchmark in the previous year increased their bid by an amount related to their distance below the benchmark. For example, a plan with a premium $10 below the benchmark in the previous year increased its bid by $8.30 in the subsequent year, all else being equal, CBO estimated. That increase was proportionately larger for plans with bids closer to the benchmark. Moreover, the bids of plans that received low-income enrollees through the automatic assignment process were less sensitive to the number of competing sponsors than were the bids of plans that did not receive low-income enrollees.

Shielding low-income beneficiaries from the costs of prescription drugs is an important objective for some policymakers, and the design of the Part D program reflects the trade-off between that objective and a desire to hold down costs to the government. The rules of the program could be altered, however, in ways that would continue to protect low-income beneficiaries but would also lower bids and government spending. For example, the government could adopt a reassignment mechanism that preferentially assigned low-income beneficiaries to the plans with premiums furthest below the benchmark; that approach would provide a stronger incentive to plans to submit low bids and would reduce the government’s spending even if plans did not alter their bids.13 Such a change, however, would probably need to be combined with a change in how the low-income benchmark was calculated. The current calculation weights bids by the number of low-income beneficiaries in each plan; as a result, if all low-income beneficiaries were reassigned to plans with premiums in the lowest 25 percent of premiums in a region, the benchmark in the next year would fall such that the number of plans that qualified for reassignment would be much smaller.

Rules for Catastrophic Drug Coverage
When a plan’s spending for a beneficiary in Part D exceeds a catastrophic threshold, the federal government reimburses the plan for 80 percent of that beneficiary’s drug spending above the threshold, and the beneficiary pays 5 percent of drug spending above the threshold. Thus, plans need to include in their bids only 15 percent of expected spending above the threshold, and plans are at risk for only 15 percent of the difference between actual spending above the catastrophic threshold and the amount of spending estimated when the plans submitted their bids. That diminished risk tempers plans’ incentives to hold down drug spending.14

The rules for catastrophic drug coverage reflect a trade-off between policymakers’ interest in protecting plans from

12. A rule that has been in force since 2011 (and was also in force in 2007 and 2008) reduces the cost to plans if their premium exceeds the benchmark. Plans with a monthly premium that exceeds the benchmark by no more than a specified amount ($2 in 2007, $1 in 2008, and $2 in 2011 and subsequent years) can reduce their premium for low-income beneficiaries to the benchmark. For plans that choose that option, no new low-income beneficiaries will be automatically assigned to them for that year, but they will not lose the low-income beneficiaries who have already enrolled.

13. Because lower-cost plans could have more restrictive formularies, an alternative to that design would be to have the government preferentially assign low-income beneficiaries to plans that had a similar formulary and premiums in the lowest 25 percent of the distribution in a region. Determining whether formularies are “similar” could be challenging, however.

14. Plans have an incentive not to overestimate spending because that would cause their premiums to rise and thus reduce enrollment.
the consequences of enrolling a disproportionate share of high-cost beneficiaries and their desire to create strong incentives for plans to restrain drug spending and thereby hold down costs to the government.\textsuperscript{15} Below the initial coverage limit ($2,850 in 2014), plans bear most of the risk if spending on drugs differs from expectations. By reducing the risk borne by plans when spending exceeds the catastrophic threshold, policymakers expected that more plans would enter the market and be less averse to enrolling beneficiaries with potentially high costs. (When the Medicare Modernization Act was enacted, private insurance companies did not generally offer stand-alone drug coverage.)

The government could strengthen the incentive for plans to better manage catastrophic drug spending by increasing the share of that spending for which the plans were responsible (and thus would factor into their bids). Under the law, the combination of direct subsidies and reinsurance covers about 75 percent of the cost of the basic benefit (with beneficiaries’ premiums covering the remainder). If the law was changed to shift costs from reinsurance into plans’ bids, reinsurance costs would fall but direct subsidies would increase, and the total government subsidy of about 75 percent of costs for the basic benefit would not change. However, such a modification might result in fewer new plan sponsors entering the market and greater efforts by plans to avoid higher-cost enrollees.

\textbf{Other Features That Lower Plans’ Risks}  
Part D includes other features that reflect the trade-off between encouraging plans to participate in the program by mitigating their financial risk and strengthening incentives for plans to control costs. The net effect of those features on the government’s spending for Part D is not clear: Implementing weaker incentives for plans to control costs tends to push up bids and therefore increase the government’s spending, but lessening plans’ risks tends to boost the number of plan sponsors in each market and therefore decrease bids and the government’s spending.

One feature that lowers plans’ risks is risk corridor payments. Plans that spend more on drugs than they anticipated by at least a specified amount receive payments from the government that cover part of those extra costs; similarly, plans that spend less on drugs than they anticipated by at least a specified amount pay the government part of those savings. Those risk corridor payments reduce a plan’s exposure to higher-than-anticipated drug spending but also decrease a plan’s gain from lower-than-anticipated drug spending. Consequently, such payments weaken the incentive for plans to aggressively reduce drug spending. Recognizing that trade-off, policymakers designed a risk corridor system that had narrow corridors for the first two years of the Part D program, when plans were more uncertain about their costs, and wider corridors thereafter. By expanding the risk corridors, policymakers lessened somewhat the adverse effects of risk corridors on plans’ incentives to hold down drug costs.\textsuperscript{16}

A second feature that reduces plans’ risks is a risk-adjustment mechanism. That mechanism assigns each beneficiary a risk score—based on the person’s medical conditions and demographic characteristics—that represents the expected drug costs for that person relative to the national average for the Medicare population. A beneficiary with a risk score of 1.0 has average expected costs. Plans receive proportionally larger or smaller payments from the government for their beneficiaries who are in worse or better health than average. However, research has shown that the risk-adjustment mechanism used for Part D before 2011 did not fully reimburse plans for beneficiaries with worse health than average (and tended to overcompensate plans for beneficiaries with better health than average); thus, despite the risk-adjustment mechanism, plans still had an incentive to attract beneficiaries with worse health than average.\textsuperscript{17} In 2011, to address those problems, program administrators updated the risk-adjustment formula; the new formula appears to


\textsuperscript{16} The thresholds of drug spending relative to anticipated spending that trigger risk corridor payments were doubled in 2008. For more on risk corridors, see Congressional Budget Office, \textit{A Detailed Description of CBO’s Cost Estimate for the Medicare Prescription Drug Benefit} (July 2004), pp. 35–37, www.cbo.gov/publication/15841.

capture the effect of health status on drug spending more accurately than the one used previously. 18

**How Payments That Plans Receive for the Basic Benefit Compare With Their Drug Spending**

Between 2007 and 2010, net payments per person to Medicare Part D plans for the basic drug benefit increased faster than the plans’ spending per person on drugs, CBO estimates. That finding implies that the sum of administrative costs and profits for plans increased between those years.

For each enrollee in a Part D plan, the federal government pays a direct subsidy to the plan and the enrollee pays a premium, the sum of which equals the plan’s bid (after adjusting for the health of the enrollee). Together, those payments account for about 70 percent of total payments to plans. In addition, the federal government makes reinsurance payments for drug costs incurred in the catastrophic phase of the benefit; they account for the remaining roughly 30 percent of total payments to plans. In addition, plans that have lower drug spending than estimated in their bid by a certain amount are required to make risk corridor payments to the government, while plans that have higher drug spending than estimated by a corresponding amount receive risk corridor payments from the government.

CBO analyzed the payments to stand-alone Part D plans and the costs incurred by those plans in each year from 2007 through 2010. The sum of direct subsidies and premiums grew at an average annual rate of 2.2 percent per person between 2007 and 2010, and reinsurance payments to plans grew at an average annual rate of 7.5 percent per person (see Table 2-1 on page 22). In each year of that period except 2008, drug spending fell far enough below the amount predicted in plans’ bids, on average, that plans paid the government between $12 and $33 per person, on net, through the risk corridor program. (In 2008, plans received payments of $6 per person from the government, on average.) In total, net payments to plans for the basic benefit grew at an average annual rate of 3.3 percent per person from 2007 to 2010. The spending by plans for drugs for the basic benefit (net of rebates) rose more slowly, at an average annual rate of 2.8 percent per person between 2007 and 2010. The difference between net payments and net drug spending, which equals the sum of administrative costs and profits, rose at an average annual rate of 6.7 percent per person between 2007 and 2010 (see Figure 2-1). CBO did not have data that enabled it to identify separate amounts for administrative costs and profits.

Determine the reasons that the sum of administrative costs and profits grew faster than drug spending for the

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### Table 2-1.
Revenues and Costs for Stand-Alone Plans Providing the Basic Benefit Under Part D, 2007 to 2010

<table>
<thead>
<tr>
<th></th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>Average Increase per Year (Percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Direct Subsidies and Premiums</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In dollars per person</td>
<td>1,064</td>
<td>1,046</td>
<td>1,111</td>
<td>1,136</td>
<td>2.2</td>
</tr>
<tr>
<td>As a percentage of total net payments to plans</td>
<td>72.3</td>
<td>68.6</td>
<td>70.6</td>
<td>70.0</td>
<td>n.a.</td>
</tr>
<tr>
<td><strong>Reinsurance</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In dollars per person</td>
<td>419</td>
<td>474</td>
<td>492</td>
<td>521</td>
<td>7.5</td>
</tr>
<tr>
<td>As a percentage of total net payments to plans</td>
<td>28.5</td>
<td>31.1</td>
<td>31.2</td>
<td>32.1</td>
<td>n.a.</td>
</tr>
<tr>
<td><strong>Risk Corridor Payments</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In dollars per person</td>
<td>-12</td>
<td>6</td>
<td>-29</td>
<td>-33</td>
<td>n.a.</td>
</tr>
<tr>
<td>As a percentage of total net payments to plans</td>
<td>-0.8</td>
<td>0.4</td>
<td>-1.8</td>
<td>-2.0</td>
<td>n.a.</td>
</tr>
<tr>
<td><strong>Total Revenues (Dollars per person)</strong></td>
<td>1,471</td>
<td>1,526</td>
<td>1,574</td>
<td>1,624</td>
<td>3.3</td>
</tr>
<tr>
<td><strong>Net Drug Spending for the Basic Benefit</strong>&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In dollars per person</td>
<td>1,272</td>
<td>1,333</td>
<td>1,348</td>
<td>1,382</td>
<td>2.8</td>
</tr>
<tr>
<td>As a percentage of total costs</td>
<td>86.5</td>
<td>87.4</td>
<td>85.7</td>
<td>85.1</td>
<td>n.a.</td>
</tr>
<tr>
<td><strong>Administrative Costs and Profits Net of Risk Corridor Payments</strong>&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In dollars per person</td>
<td>199</td>
<td>193</td>
<td>226</td>
<td>242</td>
<td>6.7</td>
</tr>
<tr>
<td>As a percentage of total costs</td>
<td>13.5</td>
<td>12.6</td>
<td>14.3</td>
<td>14.9</td>
<td>n.a.</td>
</tr>
<tr>
<td><strong>Total Costs (Dollars per person)</strong></td>
<td>1,471</td>
<td>1,526</td>
<td>1,574</td>
<td>1,624</td>
<td>3.3</td>
</tr>
</tbody>
</table>

Source: Congressional Budget Office based on data from the Centers for Medicare & Medicaid Services (CMS).

Notes: Risk corridor payments are payments made to (or from) the federal government when plans overestimate (or underestimate) their spending relative to actual spending beyond a threshold amount.

All payments are credited to the benefit year in which they were incurred, even if actual payments were received in subsequent years.

For a description of the basic benefit, see Box 2-1 on page 14.

n.a. = not applicable.

a. Net drug spending for the basic benefit includes plans' share of drug spending and reinsurance, after accounting for rebates. Using data for stand-alone Part D plans, CBO calculated net spending by subtracting total rebates received by plans from drug manufacturers (available from CMS) from the total amount that plans paid to pharmacies for spending attributable to the basic benefit (available from Part D claims data). Following the methodology used in the Medicare trustees' report for calculating per-person values, CBO divided net spending by total enrollment in stand-alone plans in July of each year to calculate net drug spending per person.

b. Administrative costs and profits net of risk corridor payments are equal to total plan payments minus net drug spending for the basic benefit.
basic benefit under the Part D program is difficult given the short time the program has been operating and a lack of information about whether the initial amounts of profits and administrative costs were unusually low. For example, profits earned in 2007 may have been unusually low—perhaps because plan sponsors initially sought to submit low bids in order to capture a greater share of the market—and the faster rate of growth afterward could just indicate a return to competitive levels of profit. In addition, administrative costs may have been unusually low at first, although one might have expected those costs to be especially high at the beginning owing to various start-up costs.

Alternatively, some of the increase in the sum of profits and administrative costs might be explained by the reduction in the number of plan sponsors, and the associated increase in bids, between 2007 and 2010. Based on CBO’s analysis of the association between the number of plan sponsors and plans’ bids, the reduction in the number of plan sponsors could explain about 13 percent of the increase in administrative costs and profits per beneficiary over the 2007–2010 period.19

19. That finding reflects the assumption that only basic plans with a premium above the low-income benchmark raised their bids in response to lower numbers of plan sponsors. To the extent that plans with a premium below the low-income benchmark or enhanced plans also raised their bids in response to lower numbers of plan sponsors, the reduction in plan sponsors could explain more of the increase in administrative costs and profits per beneficiary between 2007 and 2010.
Comparing Medicare Part D and Medicaid Fee for Service

After Medicare Part D, the largest government program for delivering prescription drug benefits is Medicaid. In 2010, about 90 percent of Medicaid’s drug benefits (in dollar terms) were provided through the fee-for-service (FFS) portion of Medicaid, which is administered by state Medicaid agencies. For simplicity, in this report, references to Medicaid are to that FFS program.

Medicare Part D and Medicaid use different approaches to contain drug prices and thus drug spending. (Throughout this chapter, unless otherwise indicated, price refers to the price net of rebates.) The competitive structure of Part D gives plan sponsors significant incentives to hold down spending, as discussed in Chapter 2. To achieve that goal, plan sponsors use three main approaches: They encourage the use of less expensive brand-name drugs, they negotiate lower prices for brand-name drugs, and they encourage the use of generic drugs. Those approaches involve influencing the behavior of beneficiaries and their doctors as well as bargaining with retail pharmacies and manufacturers of brand-name drugs to obtain lower prices net of rebates (or discounts).

By comparison, Medicaid holds down spending in two broad ways. First, the program uses an administered pricing policy, whereby drug prices are reduced relative to manufacturers’ average prices mostly through rebates that are set in federal law (rather than negotiated, as in Part D). Second, state governments—which pay a significant share of the program’s costs—have adopted a variety of strategies to control spending.

Both approaches can contain spending to some extent under certain circumstances but are less successful at doing so under other circumstances (and may have other disadvantages as well). For example, under a competitive design, the incentive to limit spending in a market with only a few plan sponsors or a falling number of plan sponsors may be weak or decreasing. (The impact on bids of the number of plan sponsors in a Part D region is described in Chapter 2.) As another example, programs with administered pricing, like Medicaid, may not be able to adjust quickly to changing market conditions. Although Medicaid’s statutory rebates represent a relatively flexible approach to administered pricing because of their link to market prices, effective implementation of the rebates can still present difficulties. Suppose that certain drugs were taken primarily by beneficiaries who were covered under programs that used such rebates; in that case, manufacturers of those drugs would have a strong incentive to raise their launch prices above what they would otherwise charge to offset the required rebates—potentially eliminating most savings from the rebate program for those drugs.

For this analysis, the Congressional Budget Office compared the average prices of drugs used in Part D and Medicaid. (Total drug spending also depends on the quantity of drugs used, but analyzing any differences in quantities in the two programs is beyond the scope of this report.) The average price of drugs in each program depends on three factors. The first factor is nationwide influences that are common to both programs—such as,

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1. The remaining 10 percent was provided by private managed care organizations. Those organizations are not included in this analysis because data about their costs and generic drug use were not available when the analysis was completed.

2. Some states also negotiate supplemental rebates. Such rebates were equal to about 4 percent of Medicaid’s total payments to retail pharmacies for brand-name drugs in 2010. Because supplemental rebates are small relative to statutory rebates (which were equal to about 54 percent of Medicaid’s total payments to retail pharmacies for brand-name drugs in 2010) and because data on supplemental rebates are not available by drug, CBO did not include them in the quantitative analyses presented in this chapter.
in recent years, the expiration of patents on existing brand-name drugs and lower rates of entry for new brand-name drugs, as discussed in Chapter 1. The second factor is the prevalence of different health conditions in the populations covered by the programs, which CBO attempted to control for indirectly in its analysis. The third factor is the approaches of the programs to containing drug spending—in particular, the actions taken by plan sponsors in Part D and the statutory rebates and actions taken by states in Medicaid. To the extent that CBO’s analysis controlled effectively for differences in health conditions between the populations covered by the programs, the remaining difference in the average prices of drugs used in Part D and Medicaid reflects the relative effectiveness of the approaches used by the programs to contain drug prices.

For the drug classes representing the great majority of drug spending by Part D beneficiaries, CBO found that Medicaid’s average price of drugs was between 27 percent and 38 percent lower than Part D’s average price in 2010 after controlling for differences in health conditions between beneficiaries of the programs. CBO expects that the difference in average prices will narrow over time as drug manufacturers respond to new rules that increased Medicaid’s rebates beginning in 2010 but that Medicaid’s average price will remain at least 20 percent to 30 percent lower than Part D’s average price after controlling for differences in beneficiaries’ health conditions.

Which end of those ranges more appropriately characterizes the relative effectiveness of the approaches used by Part D and Medicaid to contain drug prices.

Some policymakers have proposed applying Medicaid’s statutory rebates to drug purchases made by Part D beneficiaries who receive low-income subsidies (while retaining the existing structure of Part D in other respects). CBO expects that adopting such a policy would lower the average cost of brand-name drugs in Part D and thus reduce the federal government’s costs over the first decade after the policy was adopted. But a substantial portion of those savings would probably erode over time because drug manufacturers would counter the larger rebates by raising the prices for new brand-name drugs. In addition, that policy would reduce the incentive for firms to develop new drugs.

**How Medicare Part D Contains Drug Spending**

The competitive design of the Part D program creates incentives for plans to efficiently manage drug benefits in order to hold down bids and premiums and attract enrollees. Part D plan sponsors primarily use three closely related techniques to achieve those objectives:

- **Steering Beneficiaries and Their Doctors by Using a Tiered Formulary.** Plan sponsors develop formularies (lists of covered drugs) for their plans in which some drugs are in preferred tiers with lower copayments and other drugs are in nonpreferred tiers with higher copayments. That structure encourages beneficiaries to choose lower-priced drugs. In addition, plan sponsors sometimes require doctors to justify prescribing higher-priced drugs.

- **Negotiating Rebates That Lower Prices of Certain Brand-Name Drugs.** Plan sponsors often pay lower prices for brand-name drugs from manufacturers in exchange for steering beneficiaries toward those drugs by placing them in preferred tiers.
■ Encouraging the Use of Generic Drugs. Plan sponsors encourage beneficiaries to use generic drugs by setting lower copayments for those drugs. The greater use of generic drugs that results from that incentive reflects both substitution of generic drugs for their brand-name counterparts and substitution of drug therapies that offer generic alternatives for therapies that have only a brand-name version available.

Steering Beneficiaries and Their Doctors by Using a Tiered Formulary
Part D plan sponsors can encourage beneficiaries to use lower-cost drugs by creating preferred and nonpreferred tiers for brand-name drugs within their formularies. Lower copayments for drugs in the preferred tiers and higher copayments for drugs in the nonpreferred tiers encourage the use of those preferred drugs. (As explained below, generic drugs are typically placed in a separate tier with even lower copayments.) Although doctors generally determine which drug is appropriate for a patient, patients have an incentive to ask about or request alternatives when they face differing copayments.

Most Part D plans have tiered formularies with different copayments for each tier, sometimes using four or five tiers. In addition to the preferred and nonpreferred tiers for brand-name drugs, plans tend to steer beneficiaries away from the most expensive drugs—those with a retail price that exceeds $600 per prescription—by placing those drugs on a “specialty tier” for which out-of-pocket costs can be more than four times as high as for preferred drugs. Plans may also require prior authorization before drugs from the specialty tier are dispensed, or they may require that beneficiaries try generic substitutes or less expensive brand-name drugs before a more expensive drug is approved (a practice known as step therapy). Under those approaches, enrollees have an incentive to ask physicians who prescribe specialty drugs to justify the use of those costlier drugs. In 2010, across all plans that used multiple tiers to segment brand-name drugs, CBO found that about 70 percent of beneficiaries’ spending on brand-name drugs was for drugs on the preferred tiers of their plans; about 19 percent was for drugs on the nonpreferred tiers; and about 10 percent was for drugs on the specialty tier.

Researchers suggest that the negotiating leverage gained by plan sponsors because of their ability to steer beneficiaries to particular drugs has, on average, constrained the rate of growth in drug prices more for drugs for which Medicare constitutes a larger share of the drug’s market. In some instances, however, the ability of Part D plans to use their formularies to encourage beneficiaries to use less expensive brand-name drugs is limited by the statutory design of the program. For example, subsidies that cover cost sharing for most low-income beneficiaries require those beneficiaries to pay a small fixed amount for all brand-name drugs, regardless of whether those drugs receive preferred placement on a plan’s formulary. That design reflects the trade-off made by policymakers between limiting potential out-of-pocket costs for low-income beneficiaries and constraining government spending.

Negotiating Rebates That Lower Prices of Certain Brand-Name Drugs
The ability to steer beneficiaries toward preferred drugs gives Part D plan sponsors leverage when negotiating drug prices. Negotiation for drug prices within Part D occurs between plan sponsors and pharmacies for retail prices and between plan sponsors and manufacturers of brand-name drugs for additional rebates. Manufacturers would have no incentive to pay rebates if beneficiaries would use their drugs anyway, so they tend to offer the largest rebates to plan sponsors that actively steer large shares of beneficiaries to their drugs. Plan sponsors steer beneficiaries primarily by charging lower copayments for certain drugs than for others. Steering beneficiaries through copayment differentials is easiest when the drugs within a therapeutic class are close substitutes, because


5. In some cases, manufacturers might also pay a rebate to have their drug included in a plan’s formulary, even if it is not on the preferred tier.
the probability that a beneficiary’s doctor will prescribe a close substitute is relatively high; thus, rebates tend to be higher in therapeutic classes containing more drugs that are close substitutes.

Plan sponsors face some constraints in using differing copayments to steer drug use, however, particularly for drugs used by low-income beneficiaries. One approach used in some plans is to exclude from their formularies altogether some drugs that would otherwise appear on a nonpreferred tier. That approach might be particularly attractive for plans that primarily serve low-income beneficiaries, because of the constraints on copayments for covered drugs. But a plan’s ability to exclude drugs is limited because, by law and regulation, a plan must cover at least two drugs in each therapeutic class and all (or nearly all) drugs in six designated classes. Even so, that approach may have enabled some plan sponsors to negotiate large rebates for certain drugs used by low-income beneficiaries by limiting coverage of some other drugs sold at higher prices.

Encouraging the Use of Generic Drugs
Part D plan sponsors have also reduced costs by steering beneficiaries toward generic drugs instead of brand-name drugs. The primary way in which Part D plan sponsors accomplish that goal is by creating within their formularies a “generic tier” with lower copayments for generic drugs. Another way in which Part D plan sponsors sometimes steer beneficiaries toward generic drugs is by excluding brand-name drugs from coverage when generic counterparts are available.

How Medicaid FFS Contains Drug Spending
To contain drug spending, Medicaid uses two types of statutory rebates on drug purchases and a variety of actions by state governments, which administer the program.

The two statutory rebates on brand-name drugs in Medicaid together averaged 57 percent of manufacturers’ average prices in 2010. Those rebates operate as follows:

- The “basic rebate” requires manufacturers to offer a discount on their brand-name drugs that is at least 23.1 percent of the average manufacturer’s price—that is, the price that manufacturers receive before rebates for sales through retail pharmacies. (The 23.1 percent figure is thus referred to here as the “minimum rebate.”) If, however, the manufacturer offers any “qualified” purchaser in the private sector a rebate in excess of 23.1 percent, then the rebate received by Medicaid is increased to match that larger private rebate. Qualified purchasers in this case include many private-sector purchasers—such as hospitals, mail-order pharmacies, and health maintenance organizations—but exclude pharmacy benefit managers, Medicare Part D drug plans, and most other government purchasers. To enforce those requirements, manufacturers are required to report to the Centers for Medicare & Medicaid Services the lowest price paid for their drug after accounting for any rebate—known as the “best price”—if they want Medicaid to cover their drug.

- The “inflation rebate” is imposed if the average manufacturer’s price for a brand-name drug rises faster than general inflation, as measured by the consumer price index for all urban consumers (CPI-U). The average manufacturer’s price and the average retail price of

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6. The six designated classes are anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants.

7. See Department of Health and Human Services, Office of Inspector General, Concerns With Rebates in the Medicare Part D Program, OEI-02-08-00050 (March 2011), www.oig.hhs.gov/oei/reports/oei-02-08-00050.pdf (764 KB), which reports that “five of the six evaluated” sponsors received higher formulary rebates for beneficiaries eligible for the low-income subsidy than for other Part D beneficiaries” (p. 15).

8. Medicaid also requires manufacturers to pay a rebate on their generic drugs equal to 13.1 percent of the average manufacturer’s price.

9. Pharmacy benefit managers often administer drug benefits and negotiate for rebates from brand-name drug manufacturers on behalf of drug plans in the private sector, including those offered by Part D and those offered to people younger than 65. Excluding pharmacy benefit managers as qualified purchasers when those purchases are made at a community pharmacy removes roughly 80 percent of retail drug spending from the best-price calculation. However, mail-order purchases handled by pharmacy benefit managers are included in the best-price calculation. For more information about the role of pharmacy benefit managers, see Federal Trade Commission, Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies (August 2005), http://tinyurl.com/pbnf24z.
brand-name drugs typically rise faster than the CPI-U. For example, between 2007 and 2010, the average retail price of brand-name drugs in Part D increased by 8.5 percent per year, on average, whereas the CPI-U increased by 1.7 percent per year, on average. (For brand-name drugs, the retail price tends to track the manufacturer’s price but to be slightly higher.) The inflation rebate represents about half of the total rebates for brand-name drugs in Medicaid.

Because Medicaid beneficiaries have low income, their copayments for drugs are set by law and regulation to be quite small. In 2014, for example, copayments were generally about $1 to $4 per prescription and covered less than 5 percent of total drug costs. The remaining costs of drugs are divided between the federal government, which pays about 60 percent, on average, and state governments, which pay about 40 percent, on average. Thus, state governments have a significant incentive to contain drug spending. To achieve that goal, state Medicaid agencies commonly use four techniques:

- Many states encourage beneficiaries to use generic drugs by offering them at slightly lower copayments than apply to brand-name drugs. The differences between copayments tend to be small, though, because Medicaid’s copayments for prescription drugs are limited by law. That limitation protects Medicaid beneficiaries from being unable to afford to purchase certain drugs, but it also reduces the ability of states to use copayments to encourage beneficiaries to choose less expensive drugs. The limit on copayment differentials in Medicaid is similar to that in the Part D benefit for low-income enrollees.

- States’ payments to pharmacies for drugs that are available in both a brand-name version and a generic version are usually based on the cost of the generic drug plus a dispensing fee. For that reason, pharmacies have strong financial incentives to fill prescriptions using generic versions when those are available and when the prescription allows for generic substitution.

- Some states limit the use of drugs by capping the number of prescriptions that can be dispensed per month per beneficiary. In 2010, four states placed such limits on brand-name prescriptions. Those limits reduced the overall quantity of drugs used and increased the share of prescriptions filled with generic drugs. Another 14 states placed such limits on the total number of prescriptions (both brand-name and generic) per beneficiary. Those limits reduced the overall quantity of drugs used but also probably decreased the share of Medicaid-paid prescriptions filled with generic drugs, because some beneficiaries subject to the limit probably filled their prescriptions for brand-name drugs within the Medicaid program and used their own funds to pay for the less-expensive generic drugs. The remaining 32 states and the District of Columbia, which accounted for about 40 percent of total Medicaid drug spending in 2010, did not limit the number of prescriptions per beneficiary.

- Many states engage in negotiations with manufacturers to receive supplemental rebates. Manufacturers agree to pay those supplemental rebates on some brand-name drugs in exchange for states’ not requiring a beneficiary’s physician to obtain approval from a state entity before a pharmacy can dispense those drugs. Such prior-authorization requirements tend to reduce sales of the affected drugs.

Federal law prohibits state Medicaid agencies from taking certain measures to contain drug spending. For example, states may not exclude specific drugs, such as high-cost drugs, from coverage. (Private managed care organizations serving Medicaid beneficiaries, by contrast, have a greater ability to actively manage drug use by, for instance, excluding certain drugs from coverage.) Also, states cannot require significantly higher copayments for more expensive drugs.

Comparing Average Drug Prices in Medicare Part D and Medicaid

Medicare Part D and Medicaid differ in the prices they pay for drugs because the tools they use to restrain drug spending have differing effects on three variables: the

10. The four states that imposed caps on the number of brand-name prescriptions were Alabama, Illinois, Kansas, and Maine.

11. Thirteen states imposed caps on the total number of prescriptions per beneficiary: Arkansas, California, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, and West Virginia. In addition, New York placed caps on the number of prescriptions dispensed to a beneficiary that vary depending on his or her health conditions. For more detailed information on the limits that states place on Medicaid prescriptions, see Henry J. Kaiser Family Foundation, “Medicaid Benefits: Prescription Drugs” (accessed September 30, 2013), http://tinyurl.com/lgx8yza.
rebates each program receives for the same brand-name drugs, the rate of generic drug use observed in each program, and the shares of drugs used with higher and lower prices within each therapeutic class. The average prices paid for drugs in the two programs also differ because differences in the health conditions of the beneficiaries of the programs lead to different mixes of drugs being prescribed. After controlling indirectly for health conditions (in a manner described below), CBO found that the Medicaid program paid significantly lower prices in 2010 than Part D plans paid, primarily because Medicaid’s statutory rebates exceeded the rebates negotiated by plan sponsors in Part D.\textsuperscript{12}

The following subsections report the results of CBO’s analysis for each of the key variables listed—rebates, generic drug use, and the use of drugs within therapeutic classes—and then for prices overall; key caveats about the analysis are examined at the end of the section.

**Differences in Rebates**

CBO estimated that the average rebate negotiated between Part D plan sponsors and manufacturers of brand-name drugs was 15 percent of retail prices in 2010, up from 12 percent in 2007. That estimate was based on all active ingredients used by Part D beneficiaries. Several of the findings in this analysis are based on the active ingredients present in the top 53 therapeutic classes of drugs, which accounted for 70 percent of Part D spending in 2010 (see Appendix B for more information). For those active ingredients, the average Part D rebate on brand-name drugs was 17 percent in 2010, CBO found.

That rebate is much smaller than the average rebate received by Medicaid. CBO estimated that in 2010, Medicaid’s average rebate on all brand-name drugs (comprising the basic rebate and the inflation rebate) was 54 percent of retail prices; for brand-name drugs in the top 53 therapeutic classes, Medicaid’s average rebate was 56 percent.

**Differences in the Use of Generic Drugs**

The rate of generic drug use in Part D is similar to that in Medicaid, CBO found, which suggests that the tools used by those programs to encourage the use of generic drugs are about equally effective. For each of the top 53 therapeutic classes, CBO estimated the rate of generic drug use for Part D and for Medicaid; CBO then averaged rates across the 53 classes for each program using weights that matched the use of each class in Part D. Using weights based on use in Part D leads to estimates of generic drug use in Medicaid as if Medicaid beneficiaries were similar to Part D beneficiaries in their health conditions and in the consequent availability across drug classes of generic drugs to treat those conditions (see Appendix B for more information).

For the therapeutic classes CBO analyzed, the rate of generic drug use in 2010 was 75 percent within Part D and 70 percent within Medicaid (see Table 3-1). Despite the rough similarity of those overall percentages, though, the use of generic drugs in Part D and Medicaid differed substantially for many individual classes of drugs (see Table B-1 on page 41). The rate of generic drug use also varied among certain subsets of beneficiaries in the programs:

- For beneficiaries in states that cap the total number of prescriptions covered by Medicaid, claims data may understate true generic use because beneficiaries may choose to fill their prescriptions for brand-name drugs through Medicaid and their prescriptions for less-expensive generic drugs outside of the program. CBO estimated that in 2010, the average rate of generic drug use in Medicaid was 67 percent in states with caps and 74 percent in states without caps.

Stand-alone drug plans within Medicare Part D probably offer a closer comparison to Medicaid than Medicare Advantage prescription drug (MAPD) plans do, because (like Medicaid) the stand-alone plans provide a drug benefit that is administered separately from enrollees’ other medical benefits. CBO estimated that in 2010, the rate of generic drug use was 73 percent among Part D stand-alone plans and 77 percent among Medicare Advantage plans. Low-income enrollees in stand-alone plans may provide an even closer comparison to Medicaid because they have limited resources and face low copayments for drugs (as Medicaid beneficiaries do); the rate of generic drug use among low-income enrollees in stand-alone plans in 2010 was 73 percent.

- Enrollees in MAPD plans who do not receive low-income subsidies have the highest rate of generic drug

\textsuperscript{12} The price of drugs, as used in this section of the report, represents the average price (net of rebates) of brand-name drugs and generic drugs, weighted by the use of each type of drug and with drugs grouped by therapeutic class or active ingredient.
use—an estimated 78 percent in 2010—in Medicare Part D. One reason why the rate of generic use was slightly higher for beneficiaries in MAPD plans might be that those beneficiaries are usually served by physicians and other health care providers affiliated with their plan, and steering a beneficiary toward particular drugs is easier when the plan has a relationship with the physician who is prescribing the drugs. Another reason might be that, even in the absence of such relationships, MAPD plans may have doctors in their networks who are more likely to prescribe generic drugs.

Although CBO has sought to address disparate influences on the use of generic drugs in Part D and Medicaid, comparisons of the data presented here must still be interpreted with caution. For example, within the Medicaid program, some brand-name drugs may be cheaper than their generic counterparts after accounting for Medicaid’s statutory rebates—and some states discourage generic substitution in such instances. In addition, although CBO’s analysis of therapeutic classes attempts to control indirectly for differences in the prevalence of health conditions among beneficiaries in the two programs, other differences between the populations could affect their respective rates of generic drug use within a therapeutic class.

Differences in the Use of Drugs Within Therapeutic Classes

CBO found that beneficiaries of Part D tend to use less expensive drugs within therapeutic classes than do beneficiaries of Medicaid. Specifically, CBO estimated that the average price of drugs within Part D would have been 15 percent higher if the mix of drugs used within therapeutic classes matched that of Medicaid rather than that of Part D, and the average price of drugs within Medicaid would have been 15 percent lower if the mix of drugs used within therapeutic classes matched that of Medicare rather than that of Medicaid.13

The source of that difference is unclear. On the one hand, the difference might arise because the competitive design

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13. Within Medicaid, states that did not impose caps on prescriptions had a higher rate of generic drug use than the program as a whole (see Table 3-1). Considering only states without caps, CBO estimated that the average price of drugs within Part D would have been 10 percent higher if the mix of drugs used within therapeutic classes matched that of Medicaid rather than that of Part D; conversely, the average price of drugs within Medicaid would have been 12 percent lower if the mix of drugs used within therapeutic classes matched that of Part D rather than that of Medicaid. Thus, some of the difference between Part D’s and Medicaid’s use of lower-priced drugs within therapeutic classes occurred because of the lower rate of generic drug use in states that placed caps on prescriptions that could be filled within the Medicaid program.
of the Part D program creates incentives for plan sponsors to steer utilization toward lower-priced drugs in a therapeutic class through the use of formularies and differential copayments. On the other hand, the difference might arise because the prevalence of certain health conditions differs between Part D and Medicaid beneficiaries, leading the doctors of Part D beneficiaries to select less expensive drugs in a therapeutic class for nonfinancial reasons. Moreover, both explanations might be true in part. In addition, this analysis does not incorporate the effect of supplemental rebates that some states have negotiated on top of the rebates mandated by federal law, which could change the relative prices of active ingredients within therapeutic classes for Medicaid.

**Overall Difference in Average Prices**

The difference in the average prices paid for drugs by Part D and Medicaid depends on the differences in rebates, in the rates of generic drug use, and in the shares of drugs used with higher and lower prices within each therapeutic class. Average prices also depend on differences in the health conditions of the programs’ beneficiaries, which CBO tried to account for in this analysis. Specifically, CBO estimated the difference in average prices between Part D and Medicaid for the top 53 therapeutic classes using two alternative approaches.

In one approach, the agency calculated the average price of prescription drugs within each therapeutic class for each program and then averaged across classes using weights that match the use of each class in Part D.\(^{14}\) (See Appendix B for more details on CBO’s methodology.) On that basis, CBO estimated that Medicaid paid $36, on average, for a 30-day supply of drugs in 2010, whereas Part D paid $49 (see Figure 3-1).\(^{15}\) The difference of $13 amounts to a reduction of about one-quarter (27 percent) relative to the average price paid in Part D.

That comparison incorporates Medicaid’s substantially larger average rebate on brand-name drugs (56 percent, compared with 17 percent in Part D), Medicaid’s slightly lower rate of use of generic drugs (70 percent, compared with 75 percent for Part D), and Part D’s greater use of lower-priced drugs within therapeutic classes (Part D prices would be 15 percent higher under Medicaid’s use pattern). The comparison does not include supplemental rebates that some states have negotiated on top of the rebates mandated by federal law, which could change the relative prices of active ingredients within therapeutic classes for Medicaid.

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14. Across both programs, CBO calculated prices net of rebates on brand-name and generic drugs. (Rebates on generic drugs tend to be very small.) Rebate data are not available to calculate separate estimates of prices for the Part D subgroups shown in Table 3-1 (such as Medicare Advantage prescription drug plans and stand-alone plans).

15. States that did not cap prescriptions had a higher rate of generic drug use than Medicaid as a whole (see Table 3-1). Considering only states without caps, CBO estimated that the average price of a 30-day drug supply in Medicaid would have been $35.
Medicaid rebates negotiated by states, which averaged 3 percent of retail pharmacy spending in 2010; including those rebates would make the difference between drug prices under Part D and Medicaid slightly larger.

CBO also made an alternative estimate of the difference in average prices that does not include the effects of Part D’s greater use of lower-priced drugs within therapeutic classes. To exclude those effects, CBO modified its first approach by applying weights not to therapeutic classes but instead to all of the active ingredients present in those classes, with the weights based on the use of those ingredients in Part D. That second approach shows what the mix of active ingredients consumed by Medicare Part D beneficiaries would have cost at Medicaid prices—in contrast to CBO’s first approach, which shows what the mix of drug classes consumed by Medicare beneficiaries would have cost at Medicaid prices. (See Appendix B for more details.)

To understand why that alternative approach excludes the effects of Part D’s use of lower-priced drugs within therapeutic classes, suppose that a therapeutic class consisted of just two drugs with different active ingredients and that Part D beneficiaries used the drug that was less expensive more often than Medicaid beneficiaries did. For CBO’s first approach, a weight is applied to the class as a whole based on the use of that class in Part D relative to the use of other classes in Part D; in that case, the average price of drugs in that class used by Medicaid beneficiaries is increased relative to that of Part D beneficiaries by Medicaid beneficiaries’ greater use of the more expensive drug. By contrast, for CBO’s second approach, weights are applied separately to the active ingredient in each drug based on the use of that ingredient in Part D relative to the use of other ingredients in Part D; in that case, Medicaid beneficiaries’ greater use of the more expensive drug has no effect on the calculation because the weights used for those drugs are the same in calculating average prices in both Part D and Medicaid.¹⁶

Under that alternative approach, CBO estimated that Medicaid paid $31, on average, for a 30-day supply of drugs in the top 53 therapeutic classes in 2010, whereas Part D paid $49.¹⁷ The difference of $18 amounts to a reduction of more than one-third (38 percent) relative to the average price paid in Part D.¹⁸

Which of those comparisons better reflects the effect on drug prices of the different approaches to cost containment in Part D and Medicaid is unclear. To the extent that the difference in the mix of drugs used within therapeutic classes stems from the incentives in Part D, then the reduction in average prices resulting from that different mix can be attributed to the different approaches to cost containment. In that case, the estimate that Medicaid prices were, on average, 27 percent below Part D prices better captures the differing effects of the approaches of the two programs to contain drug costs. But to the extent that the difference in the mix of drugs within a class stems from differences in health conditions among Part D and Medicaid beneficiaries, then it should not be attributed to the different approaches to cost containment. In that case, the active ingredient estimate—that Medicaid prices were, on average, 38 percent below Part D prices—is the better measure of the differing approaches of the two programs to containing drug costs. Unfortunately, CBO does not have an analytic basis for identifying how much of the difference in the mix of drugs used within therapeutic classes can be attributed to each of those explanations.

Additional Caveats About This Analysis

Two issues deserve further explanation. First, the difference in average drug prices between Part D and Medicaid in 2010 partly reflects a legislative change that was implemented in that year under the Affordable Care Act. The basic rebate for Medicaid was increased in 2010 from 15.1 percent to 23.1 percent. CBO expects manufacturers to respond to that increase over time by raising their before-rebate prices for new drugs; those price increases will probably enable the manufacturers to regain a significant portion of the lost revenues. (Drugs already on the market are subject to Medicaid’s inflation rebate, so

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¹⁶. CBO’s estimate based on weights for active ingredients credits both Part D and Medicaid for using generic versions of the same active ingredients but does not credit them for using less expensive drugs with different active ingredients within the same therapeutic classes.

¹⁷. With that approach, the average price is roughly the same for states without caps on prescriptions as it is for all of Medicaid.

¹⁸. Expanding that analysis to all active ingredients (not just those in the top 53 classes), CBO estimated that the average price of a 30-day supply in 2010 was $35 in Medicaid and $54 in Part D. CBO could not make a comparable estimate for all classes weighted by the use of drugs in each class because of concerns about the accuracy of converting dosage measures of active ingredients to 30-day supplies for smaller therapeutic classes.
raising the prices of those drugs does not increase manufacturers’ net revenues from sales to Medicaid.) CBO also expects that as manufacturers raise the before-rebate prices of new drugs, they will increase rebates on those drugs for Part D to maintain similar net prices—because the increase in the Medicaid rebate will probably not have much effect on negotiating leverage between manufacturers and plan sponsors in Part D. Therefore, as sales of drugs that were launched after 2010 become an increasing share of total drug sales, the difference in average drug prices between Part D and Medicaid will diminish from what it was in 2010.

If manufacturers raised launch prices (before rebates) enough to entirely eliminate the effect of the higher basic rebate, Medicaid’s net prices would rise by about 10 percent in real (inflation-adjusted) dollars over the next two decades, holding all else equal. That change would reduce the amount by which average Medicaid prices were below average Part D prices from 27 percent to roughly 20 percent when weighted by the use of drugs in different therapeutic classes and from 38 percent to roughly 30 percent when weighted by the use of different active ingredients. However, other factors in the drug market may lead manufacturers to offset only a portion of the higher basic rebate through higher launch prices.

Second, CBO’s analysis addressed differences in the prices of drugs used in Part D and Medicaid but not differences in the quantities of drugs used. The quantities could differ because of differences in both the structures of the programs and the beneficiaries of the programs. A complete analysis of the effects of the programs’ approaches to containing drug spending would need to address the effects on quantities as well as on prices—and such an analysis would need to control for differences in the incidence and severity of various medical conditions, as well as other differences between enrollees. That analysis is beyond the scope of this report.

Applying Statutory Rebates to Medicare Part D
Some policymakers have proposed that statutory rebates similar to those in Medicaid be extended to drug pur-

19. For more information, see Congressional Budget Office, letter to the Honorable Paul Ryan about the effect of the March health legislation on prescription drug prices (November 4, 2010), www.cbo.gov/publication/21639.


suches by beneficiaries of Part D who receive low-income subsidies (while otherwise maintaining the program’s existing structure). Applying such rebates to those purchases would reduce the prices paid for drugs in Part D, especially during the first decade after those rebates were established. For example, CBO has estimated that one approach to applying Medicaid-style rebates to drug purchases by low-income beneficiaries in Part D would reduce federal spending by $123 billion from 2014 to 2023.20 Proposals of that type represent one approach to reducing the cost to the Part D program of covering low-income beneficiaries; some other approaches are discussed in Chapter 2.

Such proposals would have effects beyond the federal budget. In particular, because lower prices for Part D would reduce the expected return from drug development efforts and because manufacturers would face heightened uncertainty about the magnitude of future statutory rebates in Part D, CBO expects that the pace at which new drugs were developed would be reduced.

However, the extent of such a reduction is very uncertain.

Effects on Drug Prices
The introduction of Medicaid-style rebates into the existing Part D program would create a significant incentive for drug manufacturers to alter their pricing strategies for new drugs. Of total spending in the retail pharmacy market in 2010, Medicaid accounted for about 8 percent and Part D represented about 27 percent—with purchases by low-income beneficiaries in Part D accounting for about 15 percent and purchases by other beneficiaries in Part D accounting for about 12 percent. If the share of the market receiving Medicaid-style rebates increased from 8 percent to 23 percent (with all low-income beneficiaries in Part D included), manufacturers would have an incentive to raise the launch prices (before rebates) of new brand-name drugs to mitigate the losses in revenues from the broadening of statutory rebates. However, manufacturers...
would not be able to offset much of the effect of broader rebates on the net prices of drugs already on the market, because the inflation rebate would apply to drugs whose before-rebate prices rose faster than general inflation.

Initially, then, the prices of drugs purchased by the affected beneficiaries in Part D would probably fall to levels quite close to the current prices under Medicaid. Over time, though, manufacturers would offset much of the effect of the larger statutory rebates by launching new brand-name drugs at higher prices (before rebates), CBO anticipates. (Because the net prices to commercial buyers depend on prevailing market conditions, which would not be greatly affected by that change in Part D rules, CBO expects that manufacturers would increase the rebates offered to commercial buyers to offset much of the effect of higher before-rebate prices.) Those higher launch prices would gradually increase average drug prices for the affected beneficiaries in Part D as the pool of drugs being used changed to include more newly introduced brand-name drugs and fewer old brand-name drugs. After 15 to 20 years, CBO expects, a substantial portion of the federal savings from the statutory rebates in Part D would be offset through higher launch prices. The remaining federal savings would probably stem primarily from the inflation rebate.

Over time, prices paid by certain other purchasers would rise as well. The higher launch prices for new brand-name drugs would increase the prices paid by Medicaid. Indeed, evidence shows that Medicaid’s existing rebates have raised both the average prices and the lowest prices that are paid by private-sector purchasers.21 In addition, private-sector purchasers that received the lowest prices offered by manufacturers would see an increase in some of those prices, because a larger share of the market would have access to those prices and manufacturers would therefore have an incentive to raise the prices.

However, quantitative estimates of the effect on drug prices of imposing statutory rebates on purchases by low-income beneficiaries in Part D are very uncertain. It is difficult to predict what pricing strategies drug manufacturers would use and how manufacturers might set prices and rebates across their different market segments. Similarly, the response by consumers to higher drug prices is difficult to predict because it is influenced by many factors, including health conditions, drug innovations, advertising, drug coverage, and changes in medical technologies; factors that caused consumers to become less responsive to higher prices would enable drug manufacturers to raise launch prices more. The uncertainty becomes even greater for estimates that apply farther in the future, at which time the size and composition of the drug market might differ significantly from what they are today. For example, if new types of brand-name specialty drugs that treat complex or rare diseases and that tend not to have substitutes represented a larger share of the market, then manufacturers of those drugs might be able to more easily raise launch prices.22

Effects on the Development of New Drugs
Applying statutory rebates to drugs used by low-income beneficiaries in Part D would cause the prices paid to drug manufacturers to be much lower in the near term and somewhat lower in the long term, CBO expects. As a result, drug manufacturers would receive less income from the sale of existing drugs and lower expected profits from the development of new drugs. The reduction in prospective returns from drug development would decrease incentives to develop new drugs, particularly drugs for which a large share of users would be Medicare beneficiaries, thus making the drugs subject to the new statutory rebates.23


22. The effects discussed in this section would generally be more substantial if Medicaid-style rebates were applied to all drug purchases within Part D, not just those by low-income beneficiaries, because the scope of drug purchases that would be affected by the policy would be much larger.

In addition, the possibility that lawmakers might change the amount of the statutory rebate in the future would increase manufacturers’ uncertainty about the returns that could be earned from drug development. That uncertainty would also decrease incentives to develop new drugs.

Moreover, the reduction in current revenues would mean that manufacturers would have less money from profits available to pay for research and development. Other sources of funds, such as borrowing and issuing new stock, tend to be more costly than the internal funds made available through profits.

Taken together, the decline in the expected returns from drug development, greater uncertainty about those returns, and the higher cost of funding such development would reduce the creation of new drugs compared with what it would be under current law (that is, without broader application of statutory rebates). However, the extent to which drug development would decrease is very uncertain, for two main reasons. First, the extent to which manufacturers of brand-name drugs would offset the effect of a new statutory rebate with higher launch prices is uncertain. If manufacturers offset most of the effect of the statutory rebate, savings to the Part D program in the long term would be small but drug development in the long term would probably be only a little below what it would be under current law; however, if manufacturers offset less of the effect of the statutory rebate, savings to the Part D program would be larger but drug development would probably be diminished to a greater extent. Second, the magnitude of the effect on drug development of any given change in drug prices is uncertain. If that effect is small, then the impact of the statutory rebate on drug development might be modest; however, if that effect is large, then the impact of the statutory rebate on drug development might be sizable.

Calculating the Federal Government’s Payments and Beneficiaries’ Cost-Sharing Amounts for Medicare Part D

The cost of Medicare Part D is borne partly by the federal government and partly by beneficiaries of the program (see Figure A-1).

**Figure A-1.**
Calculating the Premiums, the Federal Government’s Payments, and Beneficiaries’ Cost-Sharing Amounts for Medicare Part D

- **Plan Sponsor’s Bid** (One bid for each plan and region): Each plan sponsor submits a bid for each plan it offers in each region. The bid is the amount the plan is willing to accept to provide the basic benefit to a beneficiary of average health minus the payments the plan expects to receive in the form of reinsurance. Separately, the plan sponsor submits an estimate of the expected reinsurance amount, which covers 80 percent of drug costs above the catastrophic threshold.

- **National Enrollment-Weighted Average Bid**: The national enrollment-weighted average bid is calculated by weighting each plan’s bid by the plan’s enrollment in the previous year.

- **National Average Reinsurance Cost**: The national average reinsurance cost is the product of the national enrollment-weighted average bid and a ratio of total expected nationwide reinsurance expenses to total nationwide bid payments.

- **Low-Income Benchmarks** (One benchmark for each region): To calculate the low-income benchmark for each region, the premiums from prescription drug plans within that region are averaged, with weights that are equal across plans in 2006 and 2007, that depend on total enrollment in 2008, and that depend on enrollment of low-income beneficiaries starting in 2009.

- **Government’s Payment and Cost-Sharing Amount for a Standard Beneficiary**:

- **Government’s Payment and Cost-Sharing Amount for a Low-Income Beneficiary**: Continued
Calculating the Premiums, the Federal Government's Payments, and Beneficiaries' Cost-Sharing Amounts for Medicare Part D

**Standard Beneficiary**

<table>
<thead>
<tr>
<th>Term</th>
<th>Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premium</td>
<td>Selected Plan Bid – (74.5% × National Enrollment-Weighted Average Bid) + (25.5% × National Average Reinsurance Cost)</td>
</tr>
<tr>
<td>Government's Payment</td>
<td>Adjusted Plan Bid – Premium for That Plan + (80% × Actual Catastrophic Spending Costs)</td>
</tr>
<tr>
<td>Cost-Sharing Amount</td>
<td>Deductible and Copayments as Determined by Plan (All basic plans must be actuarially equivalent) + (5% × Actual Catastrophic Spending Costs)</td>
</tr>
</tbody>
</table>

The selected plan bid represents the bid of the plan selected by the beneficiary. The adjusted plan bid reflects upward or downward adjustments made by the government for beneficiaries in worse or better health than average.

**Low-Income Beneficiary**

<table>
<thead>
<tr>
<th>Term</th>
<th>Formula and Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premium(^a)</td>
<td>None</td>
</tr>
<tr>
<td>Government's Payment</td>
<td>Adjusted Plan Bid + Reinsurance + Most of Standard Deductible and Copayments { If Selected Plan Premium &lt; Low-Income Benchmark }</td>
</tr>
<tr>
<td>Premium(^a)</td>
<td>Selected Plan Premium – Low-Income Benchmark</td>
</tr>
<tr>
<td>Government's Payment</td>
<td>Adjusted Plan Bid + Reinsurance + Most of Standard Deductible and Copayments { If Selected Plan Premium &gt; Low-Income Benchmark }</td>
</tr>
<tr>
<td>Cost-Sharing Amount</td>
<td>No Deductible and Small Copayments as Determined by Law</td>
</tr>
</tbody>
</table>


\(^a\) A small number of low-income beneficiaries are required to pay a larger premium than indicated.
The rules governing Medicare Part D and Medicaid fee for service differ in important ways that affect the rates of generic drug use and the prices of drugs consumed in the two programs. (Throughout this appendix, unless otherwise indicated, price refers to the price net of rebates.) Directly comparing the use and prices of drugs in the programs is not meaningful, however, because of differences between the programs' beneficiaries. The great majority of Medicare beneficiaries are older than 65 and were in a broad cross section of income brackets when they were younger; in contrast, most Medicaid beneficiaries are under 65 and have low income. As a result, the programs' beneficiaries exhibit a different mix of medical conditions and receive a different mix of drug therapies. On average, Medicaid beneficiaries tend to consume more-expensive drugs than do Medicare Part D beneficiaries (see Figure B-1). For example, the use of antipsychotic drugs (whose average prices are generally in the highest 25 percent of drug prices) is more prominent in Medicaid, whereas the use of cardiovascular drugs (whose average prices are generally in the lowest 25 percent of drug prices) is more common in Medicare.

To evaluate the two programs, the Congressional Budget Office (CBO) compared the use and prices of drugs consumed in Part D with an estimate of the use and prices of drugs consumed in Medicaid if Medicaid beneficiaries had exhibited the same distribution of drug use across therapeutic classes as did Part D beneficiaries. CBO did not calculate the average rate of generic drug use or prices of drugs actually observed in Medicaid for Medicaid beneficiaries.

For that comparison, CBO first identified the largest therapeutic classes. (Therapeutic classes offer a useful way to group active ingredients because the opportunities for substitution are similar for all of the drugs within a class.) CBO chose the 53 largest classes by starting with the 30 United States pharmacopeia (USP) therapeutic classes with the greatest Part D spending and the 30 classes with the greatest number of Part D prescriptions. That procedure resulted in 41 USP therapeutic classes defined at the broadest level. CBO further divided the drugs into 53 more-refined therapeutic classes, using the narrowest groupings of drugs available under the USP system within those 41 classes. Those 53 classes accounted for 73 percent of spending in the Part D program in 2010.

Second, CBO calculated the total number of days’ worth of drugs supplied at the national drug code (NDC) level; each NDC corresponds to a specific active ingredient, dosage form (for example, tablet or capsule), strength (10 milligrams, for instance), package size (such as 200 pills per bottle), and manufacturer. The data on Medicaid's drug use contain the number of units dispensed for the entire year but not the number of days supplied. CBO estimated the average number of days per unit in Medicaid using claims data from Part D, assuming similar numbers of units per day (such as one 10-milligram tablet each day) for Part D and Medicaid for a given active ingredient, dosage form, and strength. Multiplying the total number of Medicaid units by the estimated days per unit produced an estimate of the number of days supplied under Medicaid. NDCs representing the same active ingredient, dosage form, and strength were grouped together using Red Book data. (The Red Book is published by Truven Health Analytics, a private firm, and includes characteristics of drugs available in the United States.)
**Figure B-1.**

Comparing Use of Drugs in Medicare Part D and Medicaid Fee for Service Across Price Quartiles, 2010

Percentage of Use in Each Price Quartile

<table>
<thead>
<tr>
<th>Price Quartiles</th>
<th>Average Part D Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Quartile</td>
<td>$14</td>
</tr>
<tr>
<td>Second Quartile</td>
<td>$39</td>
</tr>
<tr>
<td>Third Quartile</td>
<td>$112</td>
</tr>
<tr>
<td>Fourth Quartile</td>
<td>$1,570</td>
</tr>
</tbody>
</table>

Source: Congressional Budget Office based on Medicare Part D claims data, Medicaid fee-for-service drug use data by state, and Red Book data (available from Truven Health Analytics).

Note: This figure divides the top 53 therapeutic classes, as described in Appendix B, into price quartiles based on a weighted average of the net Part D prices for brand-name and generic drugs within each therapeutic class. If, instead, Medicaid prices were used to determine which therapeutic classes go into which quartile, the pattern would be very similar. For Medicaid fee for service, the average net prices for each quartile in the figure are as follows: first quartile, $14; second quartile, $44; third quartile, $64; and fourth quartile, $750.

United States, such as the manufacturer’s name, product name, list price, and designation as a generic or brand-name product.) The grouped NDCs were then divided into generic and brand-name drugs.

The rates of generic drug use for Medicare Part D and Medicaid were calculated by determining the ratio of generic drugs to total drugs consumed for each therapeutic class in each program. To simulate the rate of generic drug use in Medicaid as if Medicaid beneficiaries had the same mix of drug use across therapeutic classes as that observed in Part D, CBO weighted each therapeutic class by the use of that class in Medicare Part D. (The rate of generic drug use in Medicare Part D was calculated the same way.) CBO repeated those calculations for the following programmatic subgroups: Medicaid states with and without caps on the number of prescriptions dispensed per beneficiary, Medicare stand-alone plans, Medicare Advantage prescription drug plans, Part D beneficiaries who receive low-income subsidies, and Part D beneficiaries who do not qualify for those subsidies.

Thirty-one of the top 53 therapeutic classes had rates of generic drug use between 10 percent and 99 percent for either Part D or Medicaid, as reported in Table B-1. (The results for all 53 classes together are shown in the weighted averages at the bottom of the table.) This methodology captures differences in generic substitution that occur between generic and brand-name drugs with the same active ingredients as well as differences that arise as a result of substitution between different active ingredients within a therapeutic class.

For CBO’s first approach to calculating the average prices of drugs, the average price for a 30-day supply within a class was calculated in a similar way as the use of generic drugs. CBO summed the prices for all of the drugs consumed in each therapeutic class for each program and then divided it by the total number of 30-day supplies for...
### Table B-1.
Rates of Generic Drug Use, by Selected Therapeutic Class, 2010

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Stand-Alone Plans</th>
<th>Medicare Part D</th>
<th>Medicaid Fee for Service</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LIS</td>
<td>Non-LIS</td>
<td>All Part D</td>
</tr>
<tr>
<td>Antipsychotics/Bipolar Agents</td>
<td>30</td>
<td>32</td>
<td>34</td>
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<tr>
<td>Antispasmodics/Urinary</td>
<td>39</td>
<td>38</td>
<td>43</td>
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<tr>
<td>Beta Blocking Agents</td>
<td>96</td>
<td>94</td>
<td>97</td>
</tr>
<tr>
<td>Blood Glucose Regulators</td>
<td>77</td>
<td>82</td>
<td>80</td>
</tr>
<tr>
<td>Bronchodilators</td>
<td>7</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Cardiovascular Combination</td>
<td>58</td>
<td>63</td>
<td>61</td>
</tr>
<tr>
<td>Cholinesterase Inhibitors</td>
<td>9</td>
<td>12</td>
<td>11</td>
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<tr>
<td>Dyslipidemics</td>
<td>68</td>
<td>69</td>
<td>74</td>
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<tr>
<td>Dyslipidemics/Fibric Acids</td>
<td>48</td>
<td>54</td>
<td>57</td>
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<td>Genitourinary Agents</td>
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<td>Genitourinary Agents/Hormonal</td>
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<td>61</td>
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<td>Glucocorticoids/Inflammatory Bowel</td>
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<td>Glucocorticoids/Mineralocorticoid</td>
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<td>Hormonal Agents (Thyroid)</td>
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<td>Immunological Agents</td>
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<tr>
<td>Metabolic Bone Disease Agents</td>
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<td>69</td>
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<td>Nonsteroidal Anti-Inflammatories</td>
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</tr>
<tr>
<td>Opioid Analgesics/Long Acting</td>
<td>62</td>
<td>71</td>
<td>68</td>
</tr>
<tr>
<td>Opioid Analgesics/Short Acting</td>
<td>97</td>
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<td>98</td>
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<tr>
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<td>64</td>
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</tr>
<tr>
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<td>88</td>
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</tr>
<tr>
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<td>99</td>
<td>99</td>
<td>95</td>
</tr>
<tr>
<td>Vasodilators</td>
<td>94</td>
<td>94</td>
<td>94</td>
</tr>
<tr>
<td>Weighted Average (53 top classes)</td>
<td>73</td>
<td>74</td>
<td>75</td>
</tr>
</tbody>
</table>

Source: Congressional Budget Office based on Medicare Part D claims data, Medicaid fee-for-service drug use data by state, and Red Book data (available from Truven Health Analytics) to determine whether a drug was brand-name or generic.

Notes: The use rates for generic drugs are measured as days of generic drugs supplied as shares of total days of drugs supplied and then weighted across therapeutic classes based on days supplied within Medicare Part D. The number of days supplied is estimated by multiplying the units dispensed by the days supplied per unit as estimated from Part D claims data. The 31 therapeutic classes shown here had rates of generic drug use in 2010 between 10 percent and 99 percent for either Part D or Medicaid.

LIS = low-income subsidy; GABA = gamma-aminobutyric acid; SNRI = serotonin-norepinephrine reuptake inhibitor.

a. Eighteen states capped the number of prescriptions dispensed per month per beneficiary, which changed the incentive for beneficiaries to consume generic drugs within the program and thus changed the rate of generic drug use calculated for the nation as a whole.
that program. The average prices for Part D and Medicaid were then calculated by weighting the average prices within each class by the use of that class in Part D. The resulting average prices are what would be observed for beneficiaries following the pattern of use across therapeutic classes observed for Part D beneficiaries.

For CBO’s second approach, the agency calculated the average price for a 30-day supply of drugs by dividing each therapeutic class into groups of active ingredients. In that comparison, active ingredients that had the same dosage form and strength were grouped together. The 53 classes contain 1,347 active ingredients defined in that way, which account for 73 percent of Part D spending. The average price for each program was then calculated by weighting the average price for each active ingredient by the use of the active ingredient in Part D.

2. Some states negotiate for rebates beyond the statutory rebate; those supplemental rebates, which average 4 percent of Medicaid’s retail spending on brand-name drugs, are not included in this analysis because data on the size of those rebates are not available by drug.
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About This Document

This report was prepared in response to a request from the Chairman of the Subcommittee on Health Care of the Senate Finance Committee. In keeping with the Congressional Budget Office’s (CBO’s) mandate to provide objective, impartial analysis, the report makes no recommendations.

Anna Cook of CBO’s Health, Retirement, and Long-Term Analysis Division and Andrew Stocking of CBO’s Microeconomic Studies Division wrote the report with guidance from James Baumgardner, Linda Bilheimer, and Melinda Buntin (formerly of CBO). Andrea Noda, Ellen Werble, and Rebecca Yip contributed to the analysis and provided useful comments on various drafts of the report. Tom Bradley, Phil Ellis, Holly Harvey, Tamara Hayford, Jean Hearne, Joseph Kile, and David Torregrosa also provided useful comments. Chris Zogby provided programming support. Alexia Diorio, Lydia Cox, and Sam Trachtman assisted with research and fact checking.

External reviewers of this report were Joseph Antos (of the American Enterprise Institute), Cynthia Tudor (of the Centers for Medicare & Medicaid Services), and Richard Frank (of Harvard Medical School, who at the time of the review was not in his current position with the Department of Health and Human Services). The assistance of external reviewers implies no responsibility for the final product, which rests solely with CBO.

Jeffrey Kling and Robert Sunshine reviewed the report, Christine Bogusz edited it, and Maureen Costantino and Jeanine Rees prepared it for publication. An electronic version is available on CBO’s website (www.cbo.gov/publication/45552).

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Director

July 2014