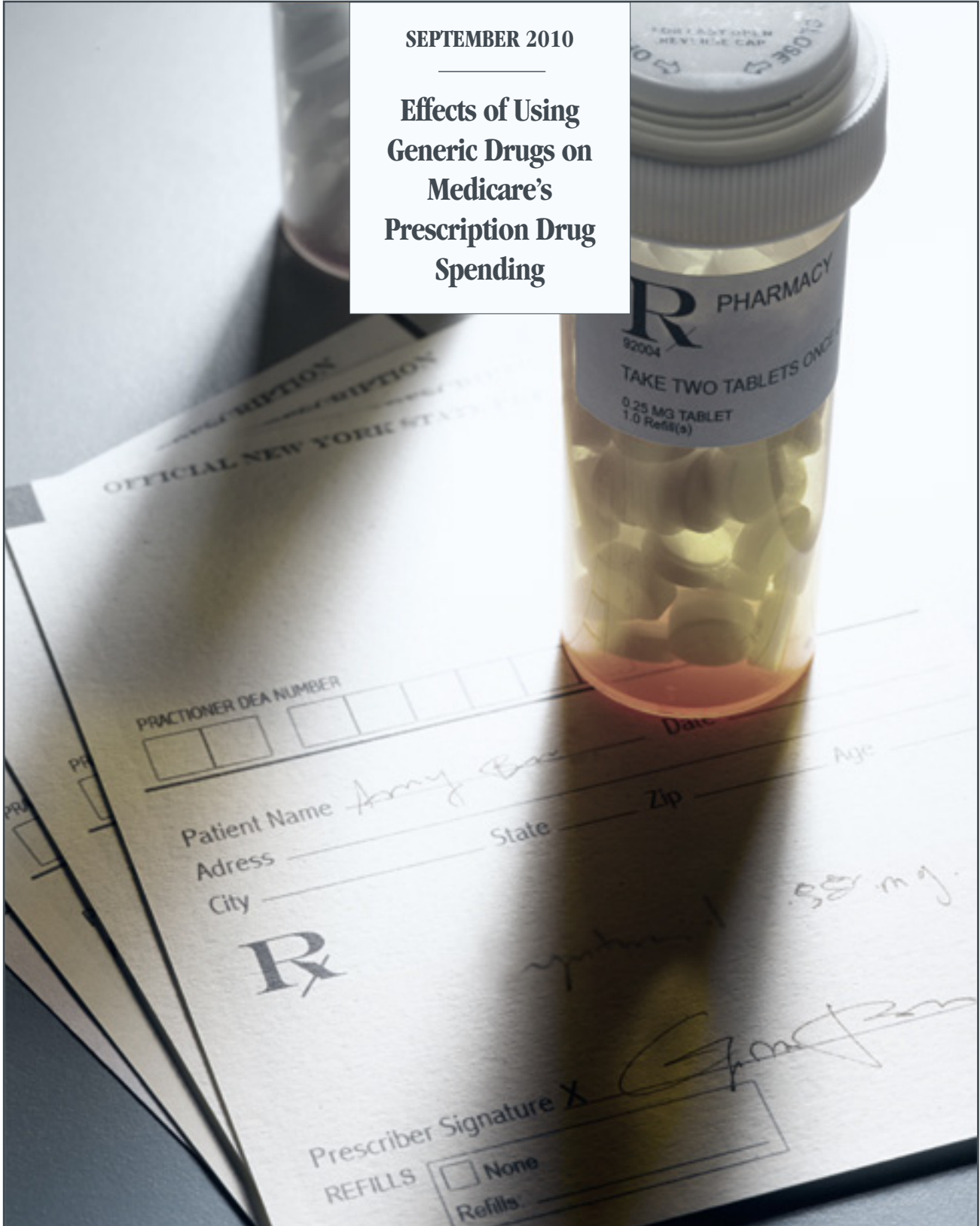


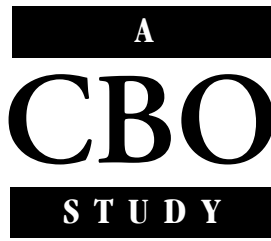
A  
**CBO**  
STUDY

SEPTEMBER 2010

**Effects of Using  
Generic Drugs on  
Medicare's  
Prescription Drug  
Spending**







# **Effects of Using Generic Drugs on Medicare's Prescription Drug Spending**

September 2010





# Preface

**M**edicare’s outpatient prescription drug benefit for senior citizens and people with disabilities, known as Part D, began in 2006. Part D uses private plans to provide coverage for prescription drugs to enrollees. The federal government does not mandate the amounts that plans pay for prescription drugs; instead, plans directly negotiate payment rates with pharmacies and rebates from drug manufacturers while competing with each other for enrollees. Such competition provides incentives for plans to control their costs. One important way in which plans seek to control costs is by encouraging the use of generic drugs. Plans can encourage enrollees to switch from brand-name drugs to their less expensive generic equivalents, a practice known as generic substitution. Plans can also encourage enrollees to switch from a brand-name drug to the generic form of a different drug that is in the same therapeutic class, one form of a practice known as therapeutic substitution.

This Congressional Budget Office (CBO) study uses data on Medicare Part D prescription drug insurance claims from the Centers for Medicare and Medicaid Services (CMS) to assess how successful plans have been in encouraging the use of generic drugs and the potential for savings from the additional use of such drugs. The study was prepared at the request of the Chairman and Ranking Member of the House Budget Committee. In keeping with CBO’s mandate to provide objective, nonpartisan analysis, this study makes no recommendations.

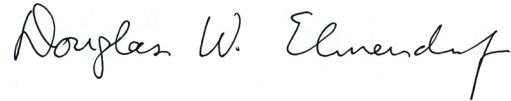
The study was written by Julie Somers of CBO’s Microeconomic Studies Division under the supervision of Joseph Kile and David Moore. Anna Cook of CBO’s Health and Human Resources Division provided useful guidance throughout and thoughtful comments on drafts. Carol Frost and Susan Labovich (both formerly of CBO) assisted with data analysis. The analysis benefited from comments provided by David Austin, Elizabeth Bass, Sheila Campbell, Julia Christensen, Phil Ellis, Justin Falk, Holly Harvey, Tamara Hayford, Daniel Kao, Kate Massey (formerly of CBO), Andrea Noda, Allison Percy, Chayim Rosito, Ellen Werble, and Rebecca Yip.

Helpful comments also came from reviewers outside CBO: Jeffrey Kelman, at CMS; Darius Lakdawalla, at the University of Southern California; Fiona Scott-Morton, at Yale School of Management; and Rachel Schmidt and Shinobu Suzuki, at the Medicare Payment Advisory Commission. (The assistance of external reviewers implies no responsibility for the final product, which rests solely with CBO.)

PREFACE

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Christine Bogusz edited the paper, and Kate Kelly proofread it. Jeanine Rees prepared the report for publication, and Maureen Costantino designed the cover. Monte Ruffin printed the initial copies, Linda Schimmel coordinated the print distribution, and Simone Thomas prepared the electronic version for CBO's Web site ([www.cbo.gov](http://www.cbo.gov)).



Douglas W. Elmendorf  
Director

September 2010



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# Summary

In 2006, Medicare began offering outpatient prescription drug benefits to senior citizens and people with disabilities in a program called Part D. Unlike other Medicare benefits covered under the traditional fee-for-service program—in which providers are paid an administratively determined price for each covered service (or bundle of services) they provide—prices in Part D are not set by the government. Instead, private plans deliver the drug benefit and negotiate their own drug prices while competing with each other for enrollees.

That framework was intended to provide those plans with incentives to make their drug benefits attractive to potential enrollees and to control their costs. One important way in which they do so is by negotiating with manufacturers of brand-name drugs for rebates. Another important mechanism is managing enrollees' use of prescription drugs—and in particular, encouraging the use of generic drugs. Using differences in copayments and other methods, plans can encourage enrollees to switch from brand-name drugs to their less expensive generic equivalents—a practice known as generic substitution. Plans can also encourage enrollees to switch from a brand-name drug to the generic form of a different drug that is in the same therapeutic class, which is one form of a practice known as therapeutic substitution. (Therapeutic substitution can also include switching from a higher priced brand-name drug to a lower priced brand-name drug in the same class.)

The Congressional Budget Office (CBO) used data from the Centers for Medicare and Medicaid Services on prescriptions filled in 2007 under Part D to assess how successful plans have been in encouraging the use of generic drugs and how much additional savings could arise from the wider use of such drugs. Developing policy tools to achieve additional savings from greater use of generic drugs is a further challenge not addressed in this study.

## Potential Savings from Generic Substitution

In 2007, total payments to plans and pharmacies from the Part D program and its enrollees were about \$60 billion. The total number of prescriptions filled under Part D was about 1 billion, of which 65 percent were filled with generic drugs, 5 percent were filled with multiple-source brand-name drugs (brand-name drugs that are also available in generic versions), and 30 percent were filled with single-source brand-name drugs (brand-name drugs for which no chemically equivalent generic versions are available). Even though a majority of prescriptions were filled with generic drugs, their lower prices meant that those prescriptions accounted for only 25 percent of total prescription drug costs.

Using the Part D data, CBO estimates that dispensing generic drugs rather than their brand-name counterparts reduced total prescription drug costs in 2007 by about \$33 billion. Thus, total payments to plans and pharmacies from the Part D program and its enrollees would have been about \$93 billion—or 55 percent higher—if no generics had been available. That analysis holds several factors constant and reflects CBO's assessment (discussed below) that generic entry is unlikely to have a substantial effect on either the price of the brand-name drug or the total quantity (including brand-name and generic versions) of the drug sold.

The savings from using generic drugs accrued to Medicare and its enrollees. In 2007, Medicare made 72 percent of the total payments to plans and pharmacies under Part D, and enrollees paid for the remainder through premiums, deductibles, coinsurance, and copayments. A reasonable judgment is that those shares of payments would also apply to the savings from generic utilization—which translates into savings of about \$24 billion for the Part D program in 2007 and about \$9 billion for its enrollees. The actual share of savings going to each group

could have been somewhat higher or lower, however, depending on a number of factors, such as how the savings altered spending across the various coverage phases of the Part D program.

CBO also analyzed the potential for additional savings from increased generic substitution and found that it is comparatively small. If all of the 45 million prescriptions filled with multiple-source brand-name drugs had instead been filled with their generic counterparts, an additional \$900 million—representing less than 2 percent of total payments to plans and pharmacies from the Part D program and its enrollees in 2007—would have been saved. Using their shares of payments to plans and pharmacies to allocate those savings, the Part D program would have saved about \$650 million, and its enrollees would have saved about \$250 million.

### Potential Savings from Therapeutic Substitution

Single-source brand-name drugs accounted for 68 percent of total prescription drug costs under Part D in 2007, even though those drugs accounted for only about 30 percent of prescriptions. Plans could have achieved some savings from that group of drugs by encouraging enrollees to switch to the generic form of a different drug in the same therapeutic class—that is, a drug designed to treat the same medical condition.

The potential to reduce costs by promoting such therapeutic substitution depends on the number of single-source prescriptions that it would be medically appropriate to switch. To assess the potential for such savings, CBO examined potential therapeutic substitution for seven therapeutic classes identified by the Medicare program as providing opportunities for such substitution. If all of the single-source brand-name prescriptions in those seven classes had been switched to generic drugs from the same class, prescription drug costs would have been reduced by \$4 billion in 2007, or 7 percent of total payments to plans and pharmacies in that year. Again using their overall shares of payments to plans and pharmacies to allocate those savings, Medicare spending would have been reduced by \$2.9 billion, and enrollees' spending would have been reduced by \$1.1 billion. As with generic substitution, the actual share of the savings going to either group could have been somewhat higher or lower.

The potential savings from therapeutic substitution to generic drugs could have been higher or lower than those

estimates, for two reasons. On the one hand, the reduction in costs in the seven therapeutic classes that feasibly could have been achieved would be less than \$4 billion because in many cases it would have been medically inappropriate to switch a prescription from a single-source brand-name drug to the generic form of a therapeutically similar drug. Some drugs in a class either may be more effective than others for some of the population or may not be safe for people with other health conditions. Consequently, a pharmacist must obtain the consent of the prescribing physician before substituting a generic drug for a single-source drug that is in the same therapeutic class but is not chemically equivalent.

On the other hand, savings from therapeutic substitution to generic drugs could have been much higher than \$4 billion to the extent that other classes of drugs also would have presented options for substitution. The seven classes that CBO evaluated represented only about one-fifth of total prescription drug costs and 15 percent of the cost of single-source brand-name drugs under Part D. Even if the share of drugs that feasibly could have been switched in those other classes had been lower than in the classes that Medicare highlighted, those switches would generate additional savings. Compared with the potential for additional savings from generic substitution, the potential for additional savings from therapeutic substitution was greater both because the savings per prescription were greater (given the relative prices of the specific drugs involved) and because slightly more prescriptions had the potential to be switched.

Policymakers would face several challenges in developing tools to achieve any additional savings from the expanded use of generic drugs—particularly in the case of therapeutic substitution. About half of Part D spending is on behalf of enrollees who have lower incomes and thus qualify for additional subsidies. Policies that used financial incentives to steer enrollees toward certain drugs might not be effective for that population because Medicare pays nearly all of their costs. In addition, plans must meet certain requirements intended to ensure that enrollees have access to the drugs that they need and to prevent the plans from discouraging beneficiaries with high drug costs from enrolling; those requirements limit plans' ability to steer drug use. Finally, it could be difficult for policymakers to design policies so that switches from single-source brand-name drugs to generic drugs were made only when medically appropriate.

## Implications of Future Developments

The estimates of actual savings from generic substitution in 2007 and potential savings that could have been realized from greater generic and therapeutic substitution during that year illustrate that using generic drugs in the future can reduce spending under Part D. However, the potential for such savings will vary from year to year depending on many factors, including the extent to which generic drugs and new brand-name drugs enter the market.

Over the next several years, entities that pay for prescription drugs will benefit from a wave of brand-name drugs in high-priced therapeutic classes losing patent protection or other periods of exclusivity, which will allow generic drugs to enter those markets for the first time. Also, relatively few new brand-name drug products are expected to reach the market in the near term. If the current rate of generic substitution is maintained, first-time generic entry occurring through 2012 will generate about \$14 billion in additional savings from generic substitution, in addition to the \$33 billion in savings calculated above (where both figures apply to 2007 spending patterns). However, potential savings from therapeutic substitution for the classes that CBO considered would be reduced from \$4 billion to about \$2 billion (also based on 2007 spending). That reduction occurs because some

of the prescriptions that would have been shifted to a different generic drug (when generating the estimate for therapeutic substitution in 2007) will have their own generic competitor by 2012; those savings are thus included in the \$14 billion figure for additional savings from generic substitution.

Two other important considerations stem from the provisions of the recently enacted legislation on health care (the Patient Protection and Affordable Care Act, as modified by the Health and Education Reconciliation Act of 2010). First and foremost, the coverage gap in the Part D benefit—a range of spending in which many enrollees have to pay all of their drug costs—will gradually be closed. As a result, the total amount of drug spending under Part D, the mix of generic and brand-name drugs used, and the federal government's share of drug spending will all change at least to some degree. In addition, the legislation created a regulatory pathway for approving drugs that are “biosimilar” to brand-name biologic products—drugs that are made from living organisms and that tend to be very expensive. How quickly those biosimilar drugs are developed and used, how they are priced, and whether they will be treated under regulation in the same manner as generic drugs for purposes of closing the coverage gap under Part D will all have important implications for future prescription drug spending.





# Effects of Using Generic Drugs on Medicare's Prescription Drug Spending

In 2006, Medicare began offering outpatient prescription drug benefits to senior citizens and people with disabilities through the Medicare Prescription Drug Benefit Program (Part D). The program relies upon private plans to deliver those benefits to its enrollees. In contrast to the traditional fee-for-service programs employed to deliver other Medicare benefits—in which providers of health care are paid an administratively determined price for each covered service, or bundle of services, that enrollees receive—prices in Part D are negotiated by private plans that compete with one another for enrollees. That framework was intended to give plans incentives to make their drug benefits attractive to potential enrollees and to control costs. Toward that end, plans use various techniques to manage enrollees' use of drugs and to negotiate price rebates from drug manufacturers and discounts from pharmacies.

Generic substitution, the practice of switching a prescription from a brand-name drug to a less expensive chemically equivalent generic drug, is one prominent approach to controlling costs.<sup>1</sup> This analysis uses data provided by the Centers for Medicare and Medicaid Services (CMS) on prescriptions filled under Part D in 2007 to assess the extent to which generic substitution reduced prescription drug spending in that year. The study also provides estimates of how much more spending could have been reduced in 2007 by additional generic substitution and by one form of another practice—known as therapeutic substitution—in which a prescription is switched from a brand-name drug to the generic form of a different drug

that is in the same therapeutic class. In addition, the outlook for future savings from using generic drugs is briefly discussed. To explain who benefits from lower prescription drug spending and the incentives of enrollees and private plans to control such spending, the study begins by describing the design of the Part D benefit, the distribution of spending under Part D, and the role of private plans in the Part D program.

## Overview of the Medicare Prescription Drug Benefit Program

Medicare Part D has about 28 million enrollees, and the Congressional Budget Office (CBO) estimates that net outlays will amount to \$48 billion in fiscal year 2010.<sup>2</sup> The program as it existed during its first five years is described below, with a particular focus on 2007 because this study uses detailed data from that year. The health care legislation enacted in March 2010 makes changes to Part D that will be phased in over a 10-year period.<sup>3</sup> The

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1. The term “chemically equivalent generic” is used throughout this study to refer to a generic drug that the Food and Drug Administration has determined is identical or bioequivalent to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.

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2. Figures exclude enrollees in and payments to plans that receive the retiree drug subsidy (a subsidy that Medicare provides to certain prescription drug plans offered by employers and union groups to their retirees). For details, see enrollment data for 2010, available at [www.cms.gov/PrescriptionDrugCovGenIn/](http://www.cms.gov/PrescriptionDrugCovGenIn/). Net outlays are spending on payment benefits minus payments from the states and the portion of premiums paid by enrollees through withholdings from Social Security benefits. (When Part D coverage began, the responsibility for paying for drugs for individuals who are enrolled in both Medicaid and Medicare shifted from the Medicaid program to the Medicare Part D program. In recognition of that change, states are required to contribute to Part D a portion of their estimated avoided drug costs for that population.)

3. Patient Protection and Affordable Care Act (Public Law 111-148) and Health Care and Education Reconciliation Act of 2010 (P.L. 111-152).

changes expected in 2011 and beyond from that legislation are also described.

### Design of the Medicare Prescription Drug Benefit

The Medicare prescription drug benefit is delivered by private plans. Private prescription drug plans—sometimes called “stand-alone” drug plans—offer only prescription drug coverage and are designed for enrollees who get their other Medicare benefits in the traditional fee-for-service program. In addition, private health plans, called Medicare Advantage plans, offer prescription drug coverage that is integrated with the health care coverage they provide to Medicare beneficiaries under Part C.<sup>4</sup>

**Original Benefit Design.** Before the recent enactment of health care legislation, the Part D standard prescription drug benefit included these phases of coverage:

- A deductible paid by the beneficiary (\$265 in 2007);
- Coverage paid by the plan for 75 percent of drug costs between the deductible and the initial coverage limit (\$2,400 in 2007);
- A coverage gap beyond the initial coverage limit in which no further coverage is provided until an enrollee has incurred out-of-pocket drug costs for the year exceeding the catastrophic threshold (\$3,850 in 2007, which corresponds to about \$5,450 in total drug spending for someone who has no supplemental drug coverage); and
- Coverage of about 95 percent of drug costs beyond that threshold, with 15 percent of those costs paid by the plan and 80 percent paid by the Part D program. That coverage is not capped.

Over time, the dollar values that set those thresholds are indexed to growth in drug spending per enrollee, so that the benefit covers roughly the same share of drug costs from year to year.

4. In addition to Part D, Medicare consists of Parts A, B, and C, which pay for other health care services for seniors and people with disabilities. Part A covers inpatient hospital stays, skilled nursing facilities, home health care, and hospice care. Part B covers outpatient hospital care, doctors' services, and many other medical services not covered by Part A. The health care services offered under Parts A, B, and D (except hospice care) can be obtained through private health plans operating under Part C. For more information on Medicare, see Hinda Chaikind and others, *Medicare Primer*, CRS Report for Congress R40425 (Congressional Research Service, March 10, 2009).

Plans may offer the standard benefit established in law, alternative prescription drug benefits that are actuarially equivalent to the standard prescription drug benefit, or benefits that are enhanced in some way. The standard benefit establishes the minimal level of coverage within Part D, but most people receive benefits that have different cost-sharing requirements—such as having a copayment that is a fixed dollar amount per prescription rather than a percentage of the prescription's cost. To be actuarially equivalent, an alternative benefit design must cover the same share of enrollees' drug costs, on average, as the standard benefit. Enhanced plans have a higher actuarial value.

For enrollees in stand-alone plans in 2007, about 20 percent were in standard benefit plans, 60 percent were in actuarially equivalent plans, and 20 percent were in enhanced benefit plans. By 2009, about 10 percent of enrollees in stand-alone plans were in standard benefit plans, 64 percent were in actuarially equivalent plans, and 26 percent were in enhanced benefit plans. Enrollees in Medicare Advantage plans were predominantly in enhanced benefit plans (80 percent in 2007 and 94 percent in 2009). Only about 1 percent of enrollees in Medicare Advantage plans were in standard benefit plans over that time period.<sup>5</sup>

For each enrollee, Medicare provides plans with a subsidy of about 75 percent of the average cost of the standard prescription drug benefit. (A portion of that subsidy is provided by paying 80 percent of drug costs above the catastrophic threshold, and the rest is made as a per-enrollee payment.) Most enrollees pay for the rest of the benefit and any enhanced benefits through premiums. Enrollees who have low income and few assets, however, may qualify for additional subsidies. For those enrollees, Medicare pays for nearly all of the premiums, deductibles, coinsurance, and copayments and for drug spending in the coverage gap.<sup>6</sup>

5. Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (March 2008), p. 290 and p. 292; and *Report to the Congress: Medicare Payment Policy* (March 2010), p. 287.

6. Enrollees qualifying for low-income subsidies are liable for additional costs if they choose plans with higher premiums than the limits set by the Centers for Medicare and Medicaid Services. Those limits ensure that enrollees will have at least one stand-alone drug plan available to them for which they do not have to pay a premium. See Patricia A. Davis, *Medicare Part D Prescription Drug Benefit*, CRS Report for Congress R40611 (Congressional Research Service, June 1, 2009), p. 12.

**Table 1.**

## Cost Sharing and Manufacturers' Discounts for Prescription Drugs in the Former Medicare Part D Coverage Gap

(Percentage of prescription drug spending)

	Brand-Name Drugs			Generic Drugs		
	Enrollees' Cost Sharing	Plans' Cost Sharing	Manufacturers' Discounts	Enrollees' Cost Sharing	Plans' Cost Sharing	Manufacturers' Discounts
2010	100.0	n.a.	n.a.	100.0	n.a.	n.a.
2011	50.0	n.a.	50.0	93.0	7.0	n.a.
2012	50.0	n.a.	50.0	86.0	14.0	n.a.
2013	47.5	2.5	50.0	79.0	21.0	n.a.
2014	47.5	2.5	50.0	72.0	28.0	n.a.
2015	45.0	5.0	50.0	65.0	35.0	n.a.
2016	45.0	5.0	50.0	58.0	42.0	n.a.
2017	40.0	10.0	50.0	51.0	49.0	n.a.
2018	35.0	15.0	50.0	44.0	56.0	n.a.
2019	30.0	20.0	50.0	37.0	63.0	n.a.
2020 and Beyond	25.0	25.0	50.0	25.0	75.0	n.a.

Source: Congressional Budget Office based on the provisions of the Patient Protection and Affordable Care Act (Public Law 111-148) and the Health Care and Education Reconciliation Act of 2010 (Public Law 111-152).

Notes: Those provisions do not apply to the prescription drug spending of enrollees with low-income subsidies or enrollees who are in plans that receive the retiree drug subsidy.

n.a. = not applicable.

Medicare also subsidizes prescription drug plans provided by employers and unions for their retirees. To qualify for that subsidy (called the retiree drug subsidy), the plans must offer benefits that are at least actuarially equivalent to the standard prescription drug benefit under Part D. As long as they meet those requirements, the plan sponsors have complete flexibility over the design of the benefits they provide.

**Recently Enacted Changes.** The recently enacted health care legislation makes several changes affecting the coverage gap in Part D. Beginning in 2011, manufacturers will be required to provide a 50 percent discount off the negotiated price of brand-name drugs included in a plan's formulary—a list of drugs that the plan will pay for—to an enrollee when his or her prescription drug spending is in the coverage gap. Those manufacturers' discounts will be counted toward enrollees' out-of-pocket costs for determining whether they have reached the catastrophic threshold. Enrollees who receive low-income subsidies or are in plans receiving the retiree drug subsidy will not be eligible for the discount (presumably because they would not have faced the coverage gap under prior law).

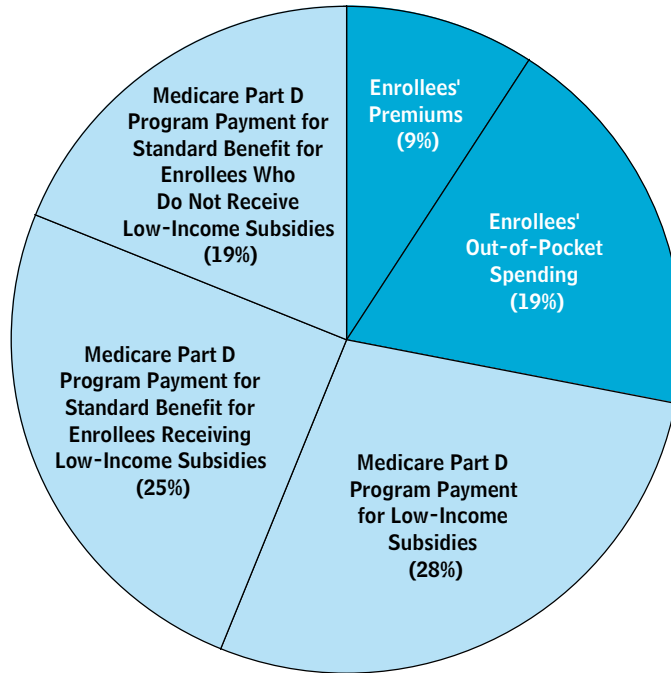
In addition, and also starting in 2011, plans will provide an increasing amount of coverage under the standard prescription drug benefit for drugs purchased in the range of spending that would have constituted the coverage gap; plans that provide an actuarially equivalent benefit will have to increase their value correspondingly. For brand-name drugs purchased in that spending range, plans will pay 2.5 percent of their cost in 2013, increasing to 25 percent by 2020 and beyond. For generic drugs purchased in that spending range, plans will pay 7 percent of the cost in 2011; that coverage will increase each year to reach a total of 75 percent by 2020, where it will remain (see Table 1). As a result, by 2020, enrollees will pay 25 percent of drug costs in the former coverage gap, just as they do in the initial phase of coverage.

### Distribution of Spending in Medicare Part D

Enrollees pay premiums to Part D plans and also pay deductibles, coinsurance, and copayments to pharmacies under the program. (Those premiums and cost-sharing requirements may be covered by third parties, such as charities or employers.) Medicare pays a premium subsidy to drug plans for all enrollees and additional subsidies for premiums and cost-sharing for low-income enrollees. All together, those payments to plans and

**Figure 1.**

**Distribution of Payments to Plans and Pharmacies for Enrollees' Prescription Drug Spending Under Medicare Part D, 2007**



Source: Congressional Budget Office based on Medicare Board of Trustees, *2010 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (August 5, 2010), p. 186, Table IV.B10, and p. 189, Table IV.B11; information from the Office of the Actuary at the Centers for Medicare and Medicaid Services; and claims data (Prescription Drug Event data) reported to the Centers for Medicare and Medicaid Services by plans.

Notes: In dollars, the total payments to plans and pharmacies (\$59.8 billion) breaks down into the following categories: \$5.5 billion for enrollees' premiums, \$11.4 billion for enrollees' out-of-pocket spending, \$16.8 billion for the Medicare Part D program benefit for low-income subsidies, \$14.6 billion for the Medicare Part D program payment for the standard benefit for enrollees receiving those subsidies, and \$11.5 billion for the Medicare Part D program payment for the standard benefit for other enrollees.

Enrollees' out-of-pocket spending includes spending by other organizations (such as charitable organizations) on an enrollee's behalf.

Medicare Part D program payments for low-income subsidies include payments for premiums made by the Part D program to plans on behalf of enrollees receiving low-income subsidies.

Medicare Part D program payments exclude payments made under the retiree drug subsidy; those payments totaled about \$4 billion in 2007.



pharmacies totaled \$59.8 billion in 2007.<sup>7</sup> (That amount excludes prescription drug spending under plans that receive the retiree drug subsidy.) Enrollees paid 9 percent of that total amount in premiums to plans and 19 percent in out-of-pocket payments to pharmacies (see Figure 1), for a total of 28 percent.<sup>8</sup> The Part D program paid 28 percent of the total for low-income subsidies beyond the standard benefit, 25 percent for the standard benefit of enrollees receiving low-income subsidies, and 19 percent for the standard benefit of other enrollees.<sup>9</sup> In sum, the Part D program paid 72 percent of the total. (As a result of the recently enacted health care legislation, the share covered by Part D will increase gradually, reaching 75 percent in 2019.)

The contribution from the Part D program differed greatly depending on whether an enrollee received a low-income subsidy. In 2007, 24 million people were enrolled in Part D (excluding those enrolled in plans that received the retiree drug subsidy). Low-income subsidies were provided to 38 percent (or 9 million) of the enrollees.<sup>10</sup> For those enrollees, the Part D program paid nearly all of the payments to plans and pharmacies. For enrollees who did

not receive those subsidies, the Part D program paid about 40 percent of the payments to plans and pharmacies.

### The Role of Private Plans in Medicare Part D

The Part D program was designed to have private plans compete for enrollees on the basis of price, access to prescription drugs, quality, and performance. Each year, plans submit bids to CMS for the cost of offering the standard benefit to an average enrollee. CMS calculates a base premium using the nationwide average bid and determines its subsidy payments on that basis. (Steps that reduce the average bid thus reduce Medicare's costs.) Enrollees must pay the base premium plus any difference between their plan's bid and the nationwide average bid. Thus, enrollees in costlier plans face higher-than-average premiums for standard Part D benefits, and enrollees in less expensive plans pay lower-than-average premiums.

Plans try to reduce the cost of providing Part D benefits by managing enrollees' use of prescription drugs, by negotiating rebates with manufacturers of brand-name drugs, and by negotiating payment rates with pharmacies. Plans can perform those functions within their organization, but often they contract them out to pharmacy benefit managers (PBMs)—similar to the way that private health plans, including health maintenance organizations and employers' plans, often use PBMs to manage pharmacy benefits on their behalf.

**Manage Enrollees' Use of Prescription Drugs.** Many plans use tiered copayments to give enrollees incentives to follow a plan's formulary and to use less expensive drugs. A three-tier copayment structure is common: Enrollees pay a low copayment for generic drugs (the first tier), a

7. Total payments to plans and pharmacies of \$59.8 billion exceeded prescription drug costs net of rebates in 2007, which CBO estimated at \$56.2 billion. The difference between the two amounts, in part, reflects administrative expenses and profits of plans. See the appendix for more details.

8. Enrollees' premiums are the sum of premiums for the standard benefit and for enhanced benefits that have greater actuarial value. Premiums for the standard benefit (or a benefit of equal actuarial value to the standard benefit) are from Medicare Board of Trustees, *2010 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (August 5, 2010), p.189, Table IV.B11, the column labeled "Premiums." For enrollees with enhanced benefits, that report includes only a portion of their premiums—the amount they would have paid if they had received a benefit of equal value to the standard benefit. Information on additional premium amounts for enrollees with enhanced benefits, which amounted to \$1.5 billion in 2007, was provided by the Office of the Actuary at CMS.

Enrollees' out-of-pocket spending is based on data on prescription drug expenditures and includes spending in the categories "Patient Pay Amount" (amounts paid by enrollees), "Other True Out-of-Pocket (TiOOP)" (for example, amounts paid by a qualified State Pharmacy Assistance Program), and "Patient Liability Reduction Due to Other Payer Amount" (for example, amounts paid by programs for workers' compensation). "True Out-of-Pocket" refers to the requirement that enrollees must generally incur out-of-pocket costs themselves (and not be reimbursed by a third party) for those costs to count toward reaching the catastrophic threshold.

9. Medicare Part D program payments to plans for the standard benefit are based on information provided by the Office of the Actuary at CMS. Part D program payments to plans for low-income subsidies are from Medicare Board of Trustees, *2010 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (August 5, 2010), p.186, Table IV.B10. They include payments for premiums, deductibles, coinsurance, and copayments made by the Part D program to plans on behalf of enrollees receiving low-income subsidies. Part D program payments exclude those made under the retiree drug subsidy, which, according to the same report, totaled about \$4 billion in 2007.

10. See Medicare Board of Trustees, *2010 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, p. 183.

higher one for preferred brand-name drugs (the second tier), and the highest copayment for nonpreferred brand-name drugs (the third tier). In 2007, the median copayments for stand-alone prescription drug plans were \$5 for generic drugs, \$28 for preferred brand-name drugs, and \$60 for nonpreferred brand-name drugs.<sup>11</sup> (In the coverage gap, many enrollees must pay the full price for their drugs, so they may have even stronger financial incentives to use less costly drugs.)

Plans may also combine formularies with other rules—such as step therapy and prior authorization—to manage enrollees' use of prescription drugs. Step therapy requires that enrollees try a cheaper generic drug or preferred brand-name drug before using a more expensive nonpreferred brand-name drug. The use of nonpreferred brand-name drugs may also require prior authorization from the plan, meaning that an enrollee's physician may have to explain why a more costly nonpreferred drug is required over a lower-cost generic or preferred brand.

About half of total prescription drug spending under Part D is on behalf of enrollees with low-income subsidies. Because those enrollees have very little cost sharing, a tiered copayment structure that relies on financial incentives may not be as effective in steering their drug use. Even so, rules such as step therapy and prior authorization could still be used to manage their drug use.

**Negotiate Rebates with Manufacturers.** Plans (or PBMs acting on their behalf) also use formularies to negotiate rebates with manufacturers of brand-name drugs. In developing its formulary, a plan determines which drugs are therapeutically similar. Then, for brand-name drugs with one or more close substitutes, the plan negotiates with manufacturers for rebates to be paid to the plan in return for placing manufacturers' drugs on the plan's preferred drug list.

In general, rebates are paid to plans for single-source brand-name drugs that are in classes containing similar drugs from which to choose. Rebates are typically not paid to plans (or are small) for multiple-source brand-name drugs and generic drugs. Once a drug is available in a generic version, pharmacists can dispense either the generic or the brand. At that point, prescription drug

plans are not in a position to promote either the multiple-source brand-name drug or the generic version, so they do not typically receive rebates on them.

Restrictive formularies that list fewer drugs in each therapeutic class will generate higher rebates than less restrictive formularies that list several drugs in each therapeutic class, because plans with more restrictive formularies will be better able to steer enrollees to a particular manufacturer's drug and away from the drug's competitors. Plans with more restrictive formularies may be less attractive to enrollees, however.

Pharmaceutical manufacturers paid rebates to prescription drug plans under Part D that totaled about \$6 billion in 2007. Costs of single-source brand-name drugs in that year totaled about \$44 billion in the Part D program. If the \$6 billion in rebates were paid primarily for single-source brand-name drugs, then rebates constituted about 14 percent of the cost of those drugs. (Unless otherwise indicated, figures for total prescription drug costs are net of those rebates.)

**Negotiate Payment Rates with Pharmacies.** Plans (or PBMs acting on their behalf) negotiate payment rates with pharmacies and seek discounts in exchange for including pharmacies in their networks. Drugs purchased at pharmacies outside a plan's network may not be covered or may require a higher copayment or coinsurance rate.

Pharmacies may be willing to accept lower payments per prescription in exchange for the greater volume of sales that can result from being part of a plan's pharmacy network. The plan's ability to achieve large discounts is greater the more restrictive the pharmacy network. However, like restrictive formularies, an overly restrictive pharmacy network may make a plan less attractive to enrollees.

**Restrictions on Private Plans in Medicare Part D.** Plans must meet certain requirements that limit their ability to reduce the costs of providing Part D benefits. Those requirements are intended to ensure that enrollees have access to the drugs that they need and to prevent plans from discouraging beneficiaries with high drug costs from enrolling. For example, some requirements concern how many drugs in a category or class of drugs must be covered; others involve having an adequate pharmacy network.

11. Patricia Neumana and Juliet Cubanski, "Medicare Part D Update—Lessons Learned and Unfinished Business," *New England Journal of Medicine*, vol. 361, no. 4 (July 23, 2009), p. 408.

Classification systems for drugs are used by plans when developing their formularies. The classification systems group drugs into therapeutic categories and pharmacologic classes of drugs that work in a similar way or are used to treat the same condition.<sup>12</sup> There are many different classification systems. “Model Guidelines” is one such system specifically developed for Medicare Part D.<sup>13</sup> Plans may adopt the Model Guidelines or may use their own classification system. A plan’s formulary must include at least two drugs in each therapeutic category and class and must include all, or substantially all, of the drugs in the following six “protected” categories or classes: anti-convulsant, antidepressant, antineoplastic, antipsychotic, antiretroviral, and immunosuppressant.

## Generic Drugs in Medicare Part D

CBO examined the use of generic drugs in Medicare Part D for calendar year 2007 using a sample of claims data containing about 10 million prescription records submitted by plans to the Centers for Medicare and Medicaid Services.<sup>14</sup> (For a description of the claims data used in the analysis, see the appendix.) CBO analyzed how much was saved as a result of the use of generic drugs and the potential for savings from increasing the use of those drugs. The analysis examined savings from generic substitution—substituting a chemically equivalent generic drug for a brand-name drug. It also examined one form of therapeutic substitution—namely, substituting a generic drug for a brand-name drug when the generic is not chemically equivalent to the brand but is in the same therapeutic class. Therapeutic substitution can also include substituting a lower priced brand for a higher priced brand that is in the same therapeutic class, but that approach is beyond the scope of this report. (For information about the role of generic drugs in the U.S. pharmaceutical marketplace more generally, see Box 1.)

12. For example, Lipitor, a top-selling drug that lowers cholesterol, is in the “cardiovascular agents” therapeutic category. That category is further subdivided into pharmacologic classes. Lipitor is in the pharmacologic class “dyslipidemics.”

13. For more about the development of the Model Guidelines, see The USP Model Guidelines Expert Committee and U.S. Pharmacopeia Staff, “Narrative Review: The U.S. Pharmacopeia and Model Guidelines for Medicare Part D Formularies,” *Annals of Internal Medicine*, vol. 145 (2006), pp. 448–453.

14. Claims data from calendar year 2007 were the most recent available for Medicare Part D when CBO’s analysis began.

## Generic Substitution

In 2007, about 65 percent of Part D prescriptions were filled with generic drugs, but those prescriptions accounted for about one-quarter of total prescription drug costs (see Table 2 on page 12).<sup>15</sup> By contrast, 30 percent of Part D prescriptions were filled with single-source brand-name drugs, but those prescriptions accounted for 68 percent of total prescription drug costs. Among Part D prescriptions written for multiple-source drugs (drugs that are available in brand-name and generic versions), more than 90 percent were filled with the generic option. That figure reflects the strong financial incentives for plans to encourage the use of generic drugs and for enrollees to use generics when available.

Those estimates for Part D of the percentage of prescriptions filled with generic drugs (65 percent) and the percentage of prescriptions written for multiple-source drugs that were filled with the generic option (more than 90 percent) are similar to estimates from other studies of the U.S. market as a whole and of Medicaid. One study found that 69 percent of prescriptions in the United States were filled with generic drugs at the end of 2008.<sup>16</sup> Another study found that 89 percent of prescriptions written for multiple-source drugs were filled with the generic option under the Medicaid program in 2004.<sup>17</sup> Other industry observers have reported that 90 percent or more of prescriptions written for multiple-source drugs were filled with the generic option under plans in the private sector by 2006.<sup>18</sup>

## Savings from Generic Substitution in Medicare Part D.

CBO estimates that, in 2007, about \$33 billion was saved because a generic drug was dispensed instead of its

15. Estimates of generic utilization can vary depending on which database of drug information is used. CBO used Thomson Micromedex’s Red Book database to classify prescription drugs as either brand-name or generic. Medi-Span and First DataBank also publish databases of drug information.

16. Generic Pharmaceutical Association, *Generic Pharmaceuticals, 1999–2008: \$734 Billion in Health Care Savings* (May 2009), p. 4.

17. Department of Health and Human Services, Office of Inspector General, *Generic Drug Utilization in State Medicaid Programs*, OEI-05-05-00360 (July 2006), p. 7.

18. Statement of Mark Merrit, Pharmaceutical Care Management Association, before the United States Senate Special Committee on Aging, *The Generic Drug Maze: Speeding Access to Affordable, Life Saving Drugs* (July 20, 2006).

**Box 1.****Generic Drugs in the U.S. Pharmaceutical Marketplace**

Generic drugs are chemically equivalent versions of brand-name drugs that can be approved under an abbreviated regulatory process once the brand's patent or other periods of exclusivity in the market expire (or the patent is successfully challenged). Manufacturers of generic drugs are not required to duplicate all of the costly clinical trials conducted by the manufacturer of the brand-name drug; instead, to gain approval from the Food and Drug Administration (FDA), they must demonstrate only that the generic version contains the same active ingredient as the brand-name version (inactive ingredients may vary) and provides very similar concentrations of the drug in the blood.<sup>1</sup> The FDA maintains that if blood concentrations are the same, the therapeutic effect will be the same, so there is no need to carry out studies for clinical effectiveness.<sup>2</sup> Even so, some groups of physicians have expressed concern that generic drugs may not work as well as their brand-name counterparts. For example, the American Academy of Neurology opposes the substitution of generic anticonvulsant drugs for the treatment of epilepsy without the attending physician's approval.<sup>3</sup>

As a result of the abbreviated regulatory process, several manufacturers of generic drugs typically enter the market when the law allows them to do so. As the number of manufacturers grows, price competition among them increases, and the average price of the generic drug relative to that of the brand-name drug declines. On average, the retail price of a generic drug is 75 percent lower than the retail price of a

1. In addition, the generic drug must be identical to the brand-name (or innovator) drug in strength, dosage form, and route of administration. It also must be indicated for the same uses; be bioequivalent; meet the same batch requirements for identity, strength, purity, and quality; and be manufactured under the same standards of the FDA's good manufacturing practice regulations required for brand-name products. See the FDA's Web site, [www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm).
2. See "Facts and Myths about Generic Drugs," [www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm).
3. See K. Liow and others, "Position statement on the coverage of anticonvulsant drugs for the treatment of epilepsy," *Neurology*, vol. 68, no. 16 (April 17, 2007), pp. 1249–1250.

**Continued**

brand-name counterpart. Thus, total payments to plans and pharmacies from the Part D program and its enrollees would have been about \$93 billion—or 55 percent higher—if no generics had been available. The estimate is based on the number of prescriptions filled with a generic drug and the observed difference between prices for brand-name drugs and the generic alternatives. The analysis holds several factors constant and reflects CBO's assessment that generic entry is not likely to have a substantial effect on either the price of the brand-name drug or the total quantity (including brand-name and generic versions) of the drug sold (see Box 2 on page 10).

Based on the data that CBO analyzed, about 600 million prescriptions were filled with a generic drug in 2007. For about 500 million of those, a multiple-source brand-name drug was available. (A brand-name drug is not always available because the manufacturer may choose to

exit the market after generic entry.) For those 500 million prescriptions, the average price (weighted by the number of generic prescriptions) of the multiple-source brand-name drugs was \$89 per prescription, whereas the average price of their generic counterparts was \$23 per prescription. The savings per prescription equals \$66—the difference between those two average prices. The savings per prescription multiplied by the 500 million prescriptions yields the estimate of about \$33 billion in savings (see Table 3 on page 13).<sup>19</sup>

19. The estimate of savings from generic substitution does not include savings from the approximately 100 million prescriptions filled with a generic drug for which there is no alternative brand available because the brand's manufacturer exited the market. Those prescriptions represent about 4 percent of total prescription drug spending.

## Box 1.

Continued

## Generic Drugs in the U.S. Pharmaceutical Marketplace

brand-name drug.<sup>4</sup> Accordingly, generic substitution—substituting a generic drug, when one is available, for a brand-name drug—is a major strategy that health insurers use to reduce their spending on prescription drugs.

Private health insurers can promote generic substitution by using a formulary (a list of covered drugs) combined with tiered copayments, charging the lowest copayment for generic drugs and a higher one for multiple-source brand-name drugs (brand-name drugs that have a generic form available). Some health insurers have formularies that exclude multiple-source brand-name drugs from coverage. However, those sorts of formularies are not very common. One 2004 survey found that about 20 percent of employees in the private sector with prescription drug benefits had no coverage for multiple-source brand-name drugs.<sup>5</sup>

Health insurers have help from pharmacists in promoting generic substitution. Generally, when a drug

is available in both generic and brand-name forms, states' laws allow pharmacists to fill the prescription with the generic even when the physician has written the prescription for the brand-name drug. Federal regulations implementing the drug benefit under Part D of Medicare also require pharmacists to notify patients if a generic substitute is available. In most states, however, the pharmacist must obtain the consent of the patient or at least must inform the patient when a generic drug is being substituted. The pharmacist cannot dispense the generic drug if the physician indicates in writing on the prescription "no substitution" or that the brand is "medically necessary."<sup>6</sup>

4. That information is based on average prescription drug costs in 2007 from the National Association of Chain Drug Stores ([www.nacds.org/wmspage.cfm?parm1=6536](http://www.nacds.org/wmspage.cfm?parm1=6536), accessed January 11, 2010).

5. The Kaiser Family Foundation and the Health Research and Educational Trust survey employers each year to examine trends in employment-based health coverage. The 2004 survey is the most recent one to include a question about mandatory use of generic drugs when available. See Kaiser Family Foundation and Health Research and Educational Trust, *Employer Health Benefits: 2004 Annual Survey* (Menlo Park, Calif., and Chicago, 2004).

6. Jack Hoadley, *Cost Containment Strategies for Prescription Drugs: Assessing the Evidence in the Literature* (report prepared for the Henry J. Kaiser Family Foundation, March 2005), p. 32.

The \$33 billion in savings was shared by enrollees and the Part D program through a combination of lower copayments and lower premiums than would have been charged otherwise, but determining the precise share that accrued to each payer is difficult. A reasonable estimate is that the savings were shared in the same proportion as total payments by those groups to plans and pharmacies in 2007 (see Figure 1 on page 4). On that basis, enrollees saved about \$9 billion (or 28 percent), and the Part D program saved about \$24 billion (or 72 percent).

The actual split of the savings between enrollees and the Part D program depends on several factors: how the savings from switching to generic drugs affects spending across the different phases of coverage, such as the coverage gap and the range of spending above the catastrophic

threshold; the mix of prices and copayments for generic drugs and their brand-name counterparts; and whether the use of generic drugs is different for enrollees who receive low-income subsidies than for the rest of the Part D population. As a result, the shares of savings for enrollees and the Part D program could have been higher or lower. For example, the share of savings that accrued to enrollees could have been higher than 28 percent if the savings from switching to generic drugs reduced spending in the coverage gap disproportionately. Alternatively, the share of savings that accrued to enrollees could have been less than 28 percent if the savings from switching to generic drugs disproportionately reduced spending for catastrophic coverage, because that spending is borne mostly by the Part D program.

**Box 2.****How Competition from Generic Drugs Affects Prices and Quantities of Prescription Drugs**

Competition from generic drugs has varied and sometimes ambiguous effects on the quantity of a drug sold (including brand-name and generic versions) and the price of the brand-name version.

**Effects on Prices**

Researchers have found that the average prices of generic drugs are much lower than the prices of brand-name drugs. As more manufacturers of generic drugs enter the market, the average price of the generic drugs relative to that of the brand-name drug declines, and the market share of the generic drugs increases.<sup>1</sup>

The effect of generic competition on the price of the brand-name drug is less clear-cut. Some studies conclude that the price of the brand-name drug increases because of competition from generics. One explanation for that effect is that some consumers are less price-sensitive than others, especially if they perceive the quality of the brand-name drug to be higher than that of its generic competitors. According to that logic, manufacturers of generic drugs compete among themselves for the price-sensitive consumers; the brand-name manufacturer retains the less price-sensitive consumers and chooses to charge them a higher price for the brand-name drug than the price before generic entry.<sup>2</sup>

Other studies conclude that competition from generics exerts a downward pressure on the price of the brand-name drug. In this story, although the price of

a brand-name drug typically increases over time after generics enter the market, the competition from generic entry causes the price of the brand-name drug to increase by less than it would have in the absence of generic entry.<sup>3</sup>

Regardless of how generic entry affects the price of the brand-name drug, the overall effect of generic entry is to decrease the average price of the drug (for brand-name and generic versions) because the prices of the generic drugs are so far below the price of the brand-name drug and because generic competitors capture a large share of the market.

**Effects on Quantities**

Typically, the total quantity of a drug sold might be expected to increase as a result of competition from generic versions because consumers typically buy more of a good when its price decreases. However, the total quantity of a drug sold may remain unchanged or may decline somewhat after generic competitors enter the market, for many reasons.<sup>4</sup> In response to anticipated generic entry, for example, manufacturers of the brand-name drug sometimes are able to modify it (by creating an extended-release version, for instance) and switch consumers to the modified and newly patented version before generic entry begins. Such a switch would reduce demand for the original drug.

1. See F.M. Scherer, "Pricing, Profits, and Technological Progress in the Pharmaceutical Industry," *Journal of Economic Perspectives*, vol. 7, no. 3 (Summer 1993), pp. 97–115.
2. See, for example, Henry Grabowski and John Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act," *Journal of Law and Economics*, vol. 35 (October 1992), pp. 331–350; and Richard Frank and David Salkever, "Generic Entry and the Pricing of Pharmaceuticals," *Journal of Economics and Management Strategy*, vol. 6, no. 1 (Spring 1997), pp. 75–90.

3. See, for example, Richard Caves, Michael Whinston, and Mark Hurwitz, "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry," *Brookings Papers on Economic Activity: Microeconomics* (1991), pp. 1–66; Jayanta Bhattacharya and William Vogt, "A Simple Model of Pharmaceutical Price Dynamics," *Journal of Law and Economics*, vol. 46 (October 2003); and Sara Fisher Ellison and others, "Characteristics of Demand for Pharmaceutical Products: An Examination of Four Cephalosporins," *RAND Journal of Economics*, vol. 28, no. 3 (Autumn 1997), pp. 426–446.
4. See Caves, Whinston, and Hurwitz, "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry."

Continued

**Box 2.****Continued****How Competition from Generic Drugs Affects Prices and Quantities of Prescription Drugs**

A decline in sales could also result if the brand-name manufacturer decreases advertising for the drug. That often occurs when generic competitors enter the market because the brand-name manufacturer is no longer able to capture all the benefits of that advertising.<sup>5</sup> Consumers may switch to a competing brand-name drug that is still advertised, or consumers with the condition may no longer use any drug therapy. A decline in quantity also could be caused by newer brands coming on the market and replacing the older drug therapy (in which case the decline is unrelated to generic entry).

Researchers have found that the overall effect of generic entry is to lower total spending on the drug (for brand-name and generic versions) because the average price is much lower.<sup>6</sup>

**Effects on Estimates of Savings**

Based on research about the effects of generic entry, the Congressional Budget Office (CBO) concluded that generic entry is not likely to have a substantial effect on either the price of the brand-name drug or the total quantity (including brand-name and generic versions) of the drug sold. CBO's estimates of savings under Part D of Medicare from generic substitution—substituting a chemically equivalent generic drug for a brand-name drug—reflect that assessment. If, instead, competition from generic drugs caused brand-name manufacturers to raise their prices, then CBO's estimates of savings might be too high. Conversely, if competition from generics caused brand-name manufacturers to lower their prices, then CBO's estimates of savings might be too low.

The estimates would also change if generic entry led to changes in the quantity of a drug sold in a specific market. If the availability of cheaper generic drugs caused the total quantity of drugs sold to increase, then the estimates of savings might be too high. If the total quantity of drugs sold declined because consumers switched to modified and newly patented versions of the brand-name drug, then spending on those new versions would offset the estimated savings from generic substitution.

In addition, changes in the marketing strategy of pharmaceutical firms producing brand-name drugs and consumers' response to those changes could affect CBO's estimates. If competition from equivalent generic drugs reduced the incentive of the manufacturer of the brand-name drug to advertise and consumers therefore switched to competing brand-name drugs, then the estimates of savings might be too high (if the competing brand drugs have a higher price than the brand with generic equivalents). Or, the estimates of savings might be too low, if the price of the competing brand drugs was lower than the price of the brand with generic equivalents. Finally, if consumers discontinued drug therapy in response to lower levels of advertising, then the estimates of savings might be too low.

More broadly, if entry by generic drugs had been prohibited—that is, if patents for drugs were essentially permanent—the market for drugs could have evolved in different ways that are very hard to predict. The types of drugs available, their prices, and their utilization rates could differ from the observed experience in ways that are not captured by studies of generic entry. Because of the uncertainties involved in predicting what would happen in that counterfactual case, CBO has not factored those possibilities into its estimate of the savings that have been achieved from generic substitution.

5. Ibid.; and Bhattacharya and Vogt, "A Simple Model of Pharmaceutical Price Dynamics."

6. See Caves, Whinston, and Hurwitz, "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry."

**Table 2.**  
**Share of Part D Prescriptions and Prescription Drug Costs, by Drug Type, 2007**

Drug Type	Percentage of Prescriptions	Percentage of Prescription Drug Costs
Generic	65	25
Multiple-Source Brand	5	7
Single-Source Brand	30	68
<b>Total</b>	<b>100</b>	<b>100</b>

Source: Congressional Budget Office based on Medicare Part D Prescription Drug Event claims data for 2007 provided by the Centers for Medicare and Medicaid Services and rebate data from the Medicare Board of Trustees, *2010 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (August 5, 2010), p. 185.

Note: Multiple-source brand refers to a drug that is sold under a brand name but is also available in generic versions from other manufacturers. Single-source brand refers to a drug that is sold under a brand name and is under patent protection—and thus is available from only one manufacturer (or occasionally from other manufacturers under license from the patent holder) and for which no chemically equivalent generic version is available.

Another complication in the analysis stems from the fact that plans were also encouraging therapeutic substitution to varying degrees (if only by using tiered copayments). Consequently, some of the \$33 billion in savings attributed to generic substitution was instead a result of therapeutic substitution. However, the amount of savings attributable to each form of substitution cannot be calculated from the available data. Because not enough is known about enrollees' medical histories or the brand-name drugs they might have been prescribed initially, it is difficult to determine when therapeutic substitutions might have occurred.

**Potential Additional Savings from Generic Substitution in Medicare Part D.** Generic substitution has produced substantial savings for Part D prescription drug spending, but the potential for additional savings from increased

generic substitution is comparatively small. If all prescriptions for multiple-source brand-name drugs had instead been filled using generic drugs, about \$900 million—or less than 2 percent of total payments to plans and pharmacies from the Part D program and its enrollees—would have been saved in 2007, CBO estimates.

That estimate was derived as follows. About 45 million prescriptions (or 5 percent) were filled with multiple-source brand-name drugs in 2007. Those drugs were most often dispensed when the difference between the price of the brand-name and generic drugs was relatively small. Specifically, the average price of multiple-source brand-name drugs was \$89 per prescription, whereas the average price of their generic counterparts (weighted by the number of multiple-source brand-name prescriptions) was \$69 per prescription. The savings per prescription equals the difference of about \$20 in the average prices. The savings per prescription multiplied by the 45 million prescriptions results in about \$900 million in potential additional savings from generic substitution (see Table 4 on page 14). Again, the analysis holds several factors constant and reflects CBO's assessment that generic entry is not likely to have a substantial effect on either the price of the brand-name drug or the total quantity (including brand-name and generic versions) of the drug sold.

The potential additional savings would have been shared by enrollees and the Part D program, but the amounts that would have accrued to each party are not known. Again, using the average shares of payments by enrollees and the Part D program to allocate those savings, about \$250 million (or 28 percent) would have accrued to enrollees, and about \$650 million (or 72 percent) would have accrued to the Part D program. Because the additional savings would have come from drugs for which the generic alternative was more expensive than average, however, the savings to the Part D program could have been less than 72 percent if the switch to a generic drug reduced enrollees' spending by a proportionately larger amount. For example, on the basis of the difference between the median copayments in 2007 for a preferred brand-name drug (\$28) and for a generic drug (\$5) and with other factors held constant, the switch from a multiple-source brand-name drug to a generic drug would have saved the enrollee \$23, but the plan would



**Table 3.****Estimate of Realized Savings from Generic Substitution, 2007**

(Dollars)

<b>Savings per Prescription</b>	
Average Price of Multiple-Source Brand-Name Drugs Weighted by the Number of Generic Prescriptions	89
Minus: Average Price of Generic Prescriptions	23
Equals: Average Savings per Prescription	66
<b>Total Savings</b>	
Average Savings per Prescription	66
Multiplied by: Number of Generic Prescriptions Filled When a Multiple-Source Brand-Name Drug Was Available (Millions)	500
Equals: Total Savings (Millions of dollars)	33,000

Source: Congressional Budget Office based on Medicare Part D Prescription Drug Event claims data for 2007 provided by the Centers for Medicare and Medicaid Services.

Note: Multiple-source brand refers to a drug that is sold under a brand name but is also available in generic versions from other manufacturers.

have paid an additional \$3. If the multiple-source brand-name drug was nonpreferred, an enrollee's savings from switching to a generic version would have been even higher.

Two considerations, however, limit the applicability of those examples. First, they apply only to prescription drug spending between the deductible and the initial coverage limit on behalf of enrollees without low-income subsidies. Nearly all of the potential additional savings on behalf of enrollees with low-income subsidies would have accrued to the Part D program because that program pays nearly all of their costs. Second, if many enrollees had made such switches, then the average share of drug costs paid by enrollees would have been reduced; although enrollees might have initially captured most of the resulting savings, the calculated actuarial value of the plan could have been increased as a result. In that case, CMS probably would have required plans to rebalance their copayment structures to maintain the same actuarial value as provided by the standard benefit design, which would have shifted some savings from enrollees to Medicare. Therefore, using the current shares of spending on Part D to allocate the savings represents a reasonable approximation of the likely outcome, at least on average.

**Therapeutic Substitution**

Single-source brand-name drugs under Part D in 2007 cost about \$38 billion. Some savings could have been achieved from that group of drugs by switching enrollees from a higher priced brand-name drug to a lower priced

brand-name or generic drug that is not chemically equivalent but is in the same therapeutic class, a practice known as therapeutic substitution.

Using a tool called the "Medicare Prescription Drug Plan Finder," CBO analyzed one form of therapeutic substitution—switching an enrollee from a single-source brand-name drug to the generic form of a different drug that is in the same therapeutic class. The main purpose of the Medicare Prescription Drug Plan Finder is to help Medicare beneficiaries compare the total prices of plans on the basis of the drugs they take—counting not only the premium they would have to pay but also each plan's cost-sharing requirements for those specific drugs. The tool also indicates when generic versions of drugs are available and provides information to beneficiaries on lower priced drugs that could be substituted for higher priced drugs in 15 classes and subclasses. The majority of those classes and subclasses are for drugs that treat cardiovascular diseases (for example, high cholesterol and high blood pressure). Also included in the list are classes and subclasses of drugs that treat gastrointestinal diseases and allergies.

CBO calculated potential savings from therapeutic substitution for 7 of the 15 therapeutic classes identified by the drug finder as offering opportunities for such substitution (see Table 5 on page 15). Those seven classes were chosen because they contained at least one single-source brand-name drug and one therapeutically similar drug that was also available in a generic form. There were about 180 million prescriptions written for drugs in the seven classes and subclasses in 2007, totaling about

**Table 4.****Potential Additional Savings from Generic Substitution, 2007**

(Dollars)

<b>Savings per Prescription</b>	
Average Price of Multiple-Source Brand-Name Drugs	89
Minus: Average Price of Generic Drugs Weighted by the Number of Multiple-Source Brand Prescriptions	69
Equals: Average Savings per Prescription	20
<b>Total Potential Savings</b>	
Average Savings per Prescription	20
Multiplied by: Number of Multiple-Source Brand Prescriptions Filled When a Generic Drug Was Available (Millions)	45
Equals: Total Potential Additional Savings (Millions of dollars)	900

Source: Congressional Budget Office based on Medicare Part D Prescription Drug Event claims data for 2007 provided by the Centers for Medicare and Medicaid Services.

Note: Multiple-source brand refers to a drug that is sold under a brand name but is also available in generic versions from other manufacturers.

\$10 billion in prescription drug costs. That amount represents about 17 percent of total payments to plans and pharmacies from the Part D program and its enrollees. About 66 percent of the prescriptions in the seven classes were dispensed with generic drugs, accounting for 36 percent of prescription drug costs in those classes. About 30 percent of the prescriptions were filled with single-source brand-name drugs, which were 59 percent of prescription drug costs in those classes (see Table 6 on page 16). For prescriptions written for multiple-source drugs, 95 percent were filled with the generic option.

Focusing on those seven therapeutic classes, CBO determined that switching a prescription in 2007 from a single-source brand-name drug to a generic drug in the same class would have reduced the cost of each prescription by about 70 percent, on average. On the one hand, the potential to increase savings through therapeutic substitution would have been limited by the number of single-source prescriptions that it would have been medically appropriate to switch. On the other hand, savings might also have been feasible in other classes of drugs, but the difference in prices and the extent of the opportunities for therapeutic substitution would have differed in those classes.

**Potential Savings from Therapeutic Substitution in Certain Drug Classes.** Prescription drug spending for single-source drugs totaled about \$5.8 billion (net of rebates) in 2007 in the seven classes that CBO consid-

ered. In the claims data that CBO analyzed, the price of a single-source brand-name drug was \$128 per prescription, on average. Because plans received rebates from manufacturers that averaged about 14 percent of single-source prescription drug spending, the average price of a single-source brand-name prescription minus rebates was about \$110. The average price of generic drugs in those seven classes (weighted by the number of single-source prescriptions in each class) was \$34 per prescription, or about 70 percent lower than the average price of the single-source brand-name drugs. Thus, the average savings per prescription from switching equals \$76.

There were 53 million single-source brand-name prescriptions in those classes. If all had been switched to generics from the same class, then multiplying by the savings per prescription would yield a potential reduction in prescription drug spending of about \$4 billion (see Table 7 on page 17).<sup>20</sup> That reduction would have been about

20. The potential additional savings from therapeutic substitution are based on the difference between the price per prescription for the single-source brand-name drug and the average price per prescription for all generic drugs in the same therapeutic class. CBO also estimated savings for each class and subclass using other measures: the average price for a 30-day supply of generic drugs, the lowest price for a generic prescription, the lowest price for a 30-day supply of generic drugs, the price of the most frequently used generic prescription, and the price of the most frequently used generic drug based on the number of days supplied. The estimates of savings varied little between methodologies.

**Table 5.**  
**Selected Classes of Drugs Analyzed for Possible Therapeutic Substitution**

**Cardiovascular Agents**

HMG CoA reductase inhibitors (statins)  
 Angiotensin-converting enzyme (ACE) inhibitors  
 Calcium channel blocking agents, dihydropyridines  
 Calcium channel blocking agents, nondihydropyridines  
 Nonselective beta-adrenergic blocking agents

**Gastrointestinal Agents**

Proton pump inhibitors

**Respiratory Tract Agents**

Mildly/nonsedating histamine<sub>1</sub> (H<sub>1</sub>) blocking agents

Source: Congressional Budget Office based on information provided by the Centers for Medicare and Medicaid Services.

Notes: The Congressional Budget Office selected these seven classes and subclasses because they contained at least one single-source brand drug and a therapeutically similar drug that is also available in a generic form in 2007. Single-source brand refers to a drug that is sold under a brand name and is under patent protection—and thus is available from only one manufacturer (or occasionally from other manufacturers under license from the patent holder) and for which no chemically equivalent generic version is available.

This analysis excludes combination drugs and drugs that have alpha receptor activity or intrinsic sympathomimetic activity.

7 percent of total payments to plans and pharmacies from the Part D program and its enrollees in 2007. The analysis holds several factors constant and reflects CBO's assessment that generic entry is not likely to have a substantial effect either on the price of the brand-name drug or on the total quantity (including brand-name and generic versions) of the drug sold.

The potential reduction of \$4 billion in prescription drug spending would have been shared by enrollees and the Part D program. Again applying the shares of payments by those groups to plans and pharmacies in 2007 (see Figure 1 on page 4), enrollees' spending would have been reduced by \$1.1 billion (or 28 percent), and the Part D program's spending would have been reduced by \$2.9 billion (or 72 percent). The shares of those savings that would have accrued to both parties could have been higher or lower in actuality, however. In particular, shares of savings for any subset of therapeutic classes could have differed from average shares calculated for all classes.

**Medical Appropriateness of Therapeutic Substitution.**

The savings that feasibly could have been achieved from therapeutic substitution in those classes of drugs would have been smaller than \$4 billion because it would have been medically inappropriate, in many cases, to make such switches. Within a therapeutic class, drugs may be approved by the Food and Drug Administration (FDA) to treat different symptoms and diseases. For example, within the class of drugs known as "nonselective beta-adrenergic blocking agents" (used for treating high blood pressure) is a subset of drugs that is also approved for treating migraines. The physician of a patient with migraines may not be willing to write a new prescription for a generic drug in that class of blocking agents if the drug has not been approved by the FDA to treat migraines.

Even among drugs approved to treat the same condition, important differences can exist. Some drugs in a class may be more effective than others, at least for some members of the population. Certain subpopulations—for example, people with liver or kidney disease—may need a specific brand-name drug in a class. In addition, some drugs in a class may have harmful side effects for different patients. Depending on the drug, side effects can range from relatively mild (such as dry mouth and drowsiness) to more severe (such as nausea and headaches) to life threatening (such as seizures, difficulty breathing, and liver damage). Moreover, drugs may have different dosing regimens, and physicians may be concerned about a reduction in patient compliance if they switched to drugs that must be taken more frequently. Also, physicians and their patients may be reluctant to switch to a therapeutic alternative once a condition has been stabilized using a brand-name drug. Finally, physicians' clinical experience with their patients may lead them to conclude that certain patients respond better to a particular drug from a given class.

Reflecting those considerations, a pharmacist must obtain the consent of the prescribing physician before substituting a generic drug for a single-source drug that is not chemically equivalent but is in the same therapeutic class. In contrast, a pharmacist can generally substitute a chemically equivalent generic drug for its brand-name counterpart without contacting the physician.

The claims data that CBO used do not contain enough information to determine the percentage of prescriptions for which therapeutic substitution would have been

**Table 6.**  
**Percentage of Part D Prescriptions and Prescription Drug Costs, by Drug Type, in Seven Selected Classes and Subclasses, 2007**

Drug Type	Percentage of Prescriptions	Percentage of Prescription Drug Costs
Generic	66	36
Multiple-Source Brand	4	5
Single-Source Brand	30	59
<b>Total</b>	<b>100</b>	<b>100</b>

Source: Congressional Budget Office based on Medicare Part D Prescription Drug Event claims data for 2007 provided by the Centers for Medicare and Medicaid Services and rebate data from the Medicare Board of Trustees, *2010 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (August 5, 2010), p. 185.

Note: Multiple-source brand refers to a drug that is sold under a brand name but is also available in generic versions from other manufacturers. Single-source brand refers to a drug that is sold under a brand name and is under patent protection—and thus is available from only one manufacturer (or occasionally from other manufacturers under license from the patent holder) and for which no chemically equivalent generic version is available.

medically appropriate. That analysis would require detailed information about the incidence of diseases and other conditions in the Part D population and a thorough review of disease-treatment guidelines. However, examining potential savings by class provides some additional insight. Almost all of the potential savings from therapeutic substitution were concentrated in two of the seven classes that CBO examined: Proton pump inhibitors accounted for about 50 percent of the potential savings, and statins accounted for 44 percent. That concentration of savings resulted from the high percentages of prescriptions filled with single-source brand-name drugs in the two classes relative to the others—as well as the large number of prescriptions written for those widely used drugs.

Proton pump inhibitors are used to treat chronic symptoms of heartburn or acid regurgitation (known as gastro-

esophageal reflux disease) and to treat and prevent ulcers.<sup>21</sup> Research indicates that drugs in that class are similar in safety and effectiveness when compared at equivalent doses.<sup>22</sup> That finding would indicate that a large share of single-source prescriptions could be switched to generic proton pump inhibitors.

Statins are used to lower cholesterol. High cholesterol can increase the risk of a heart attack and death from heart disease or stroke. Statins differ by how much of a reduction in cholesterol they provide. Enrollees who require large reductions to achieve desired blood concentrations would probably require a brand-name statin.<sup>23</sup> Although one health plan reported that more than 75 percent of patients taking a statin could achieve their cholesterol-lowering goals using a generic statin, specific information on the population of Medicare enrollees taking single-source brand-name statins would be needed to determine if the use of generic drugs could be increased among that population.<sup>24</sup>

**Application to Other Drug Classes.** For other reasons, potential savings from therapeutic substitution could have been higher than \$4 billion. The seven classes that CBO examined accounted for only 17 percent of total prescription drug costs in 2007 and only about 15 percent of the costs of single-source brand-name drugs under Part D. To the extent that other classes also present opportunities for therapeutic substitution, potential savings would increase. Additionally, this analysis considered just one form of therapeutic substitution. If potential savings from substituting lower priced brands for higher priced brands in the same therapeutic class were also considered, then those savings would increase.

21. Proton pump inhibitors are also available in low doses over the counter. Those versions are approved by the FDA only to treat infrequent symptoms of heartburn.
22. Kenneth DeVault and Donald Castell, "Updated Guidelines for the Diagnosis and Treatment of Gastresophageal Reflux Disease," *American Journal of Gastroenterology*, vol. 100 (2005), pp. 190–200.
23. Drug Effectiveness Review Project, Drug Class Review, *HMG-CoA Reductase Inhibitors (Statins) and Fixed-Dose Combination Products Containing a Statin, Final Report Update 5*, Oregon Health and Science University (November 2009).
24. Emily Cox, Andy Behm, and Doug Mager, *2005 Generic Drug Trend Usage Report* (St. Louis, Mo.: Express Scripts).

**Table 7.****Potential Savings from Therapeutic Substitution for Seven Selected Drug Classes, 2007**

(Dollars)

<b>Savings per Prescription</b>	
Average Price of Single-Source Brand-Name Drugs, Net of Rebates <sup>a</sup>	110
Minus: Average Price of Generic Drugs Weighted by the Number of Single-Source Brand Prescriptions	34
Equals: Potential Additional Savings per Prescription	76
<b>Total Potential Savings<sup>b</sup></b>	
Potential Additional Savings per Prescription	76
Multiplied by: Number of Single-Source Brand Prescriptions Filled When a Generic Drug Was Available (Millions)	53
Equals: Total Potential Savings <sup>b</sup> (Millions of dollars)	4,028

Source: Congressional Budget Office based on Medicare Part D Prescription Drug Event claims data for 2007 provided by the Centers for Medicare and Medicaid Services and rebate data from the Medicare Board of Trustees, *2010 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (August 5, 2010), p. 185.

Note: Single-source brand refers to a drug that is under patent protection and is sold under a brand name—and thus is available from only one manufacturer (or occasionally from other manufacturers under license from the patent holder). No chemically equivalent generic version is available.

- a. Plans received rebates from manufacturers that averaged about 14 percent of single-source prescription drug costs in 2007.
- b. Potential savings are higher than the actual amount would be; in many cases, it would be medically inappropriate to switch a patient's prescription from a single-source brand in one of the seven classes to a generic in the same class.

The range of rates for the utilization of generic drugs across plans in Part D may provide some insight into the potential for switching prescriptions from single-source brands to generic alternatives across all therapeutic classes. Although the overall share of prescriptions filled with generic drugs was about 65 percent under Part D in 2007, it generally ranged from about 55 percent to about 70 percent among stand-alone drugs plans, and it reached somewhat higher rates in some integrated health plans—indicating that the degree to which plans are promoting the use of generics over brands varies widely, so there may be room for plans with low rates of generic utilization to increase them.<sup>25</sup> (However, the differences in rates of generic utilization could also stem from differences in the population of enrollees in each plan.)

### Comparing Potential Savings from Generic and Therapeutic Substitution

CBO's analysis of claims data from 2007 indicates that the potential for additional reductions in prescription

drug spending is greater with therapeutic substitution than with the more straightforward generic substitution—although as noted above, the challenges in achieving those savings may also be greater for therapeutic substitution. In that analysis, therapeutic substitution resulted in higher savings primarily because the cost of a generic prescription was about 70 percent lower than that of a single-source brand-name prescription in the same therapeutic class (for the classes examined), whereas the cost of a generic prescription was only about 20 percent lower than the cost of a multiple-source brand-name prescription, on average.

Several factors explain that difference in potential savings. First, single-source brand-name drugs are generally newer and often represent improvements (real or perceived) over multiple-source brand-name drugs that treat the same condition, and their patent protection thus allows their manufacturers to charge prices that are typically higher than those charged for older drugs; that increases the potential savings from therapeutic substitution. Furthermore, when multiple-source brand-name drugs were dispensed, the prices of their generic counterparts were higher than the average price of all generic drugs that had

25. Rates of utilization of generic drugs by plan are based on data from CMS (see [www.cms.hhs.gov/PrescriptionDrugCovGenIn/06\\_PerformanceData.asp#TopOfPage](http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp#TopOfPage)).

been dispensed, which limits the potential additional savings from generic substitution. Moreover, the number of prescriptions under Part D that could be switched to a generic drug through therapeutic substitution was slightly greater than the number that could be switched through generic substitution—largely reflecting the extensive use of generic substitution that has already occurred. An offsetting consideration is that it would be medically inappropriate to practice therapeutic substitution in many cases, which is one factor that would reduce the actual savings that could be obtained from that approach.

Policymakers would face several challenges in developing tools to achieve any additional savings from the expanded use of generic drugs—particularly in the case of therapeutic substitution. About half of Part D spending is on behalf of enrollees who have lower income and thus qualify for additional subsidies. Policies that used financial incentives to steer enrollees toward certain drugs might not be effective on that population because Medicare pays nearly all of their costs. In addition, plans must meet certain requirements intended to ensure that enrollees have access to the drugs that they need and to prevent the plans from discouraging beneficiaries with high drug costs from enrolling; those requirements limit plans' ability to steer drug use. Finally, it could be difficult for policymakers to design policies so that switches from single-source brand-name drugs to generic drugs were made only when medically appropriate.

## Implications of Future Developments

The estimates of actual savings from generic substitution and potential savings from additional generic and therapeutic substitution in 2007 provide some insight into how much savings could be obtained in the future through the increased use of generic drugs. However, some changes in the pharmaceutical marketplace have already occurred—and many others could occur—that might affect actual and potential savings from the increased use of generic drugs. In addition, changes introduced by the recently enacted health care legislation will direct a larger share of any savings that are achieved to the Medicare Part D program because the program will cover an increasing share of prescription drug spending as the coverage gap closes.

Two factors may hold down prescription drug spending in the near term. First, payers will benefit from a wave of

brand-name drugs in high-priced therapeutic classes losing patent protection or other periods of exclusivity, allowing first-time generic entry. Second, relatively few new brand-name drug products are expected to reach the market over the next few years.

A countervailing factor is that analysts expect to see a rapid increase in spending under Part D for a particular category of drugs called biologics. Those drugs, which are derived from living organisms, can be particularly expensive. The recently enacted health care legislation created a regulatory pathway for approving less expensive alternatives to those drugs, but in certain circumstances enrollees in Part D may have limited incentives to use them and drug plans may have limited incentives to encourage their use.

## First-Time Generic Entry

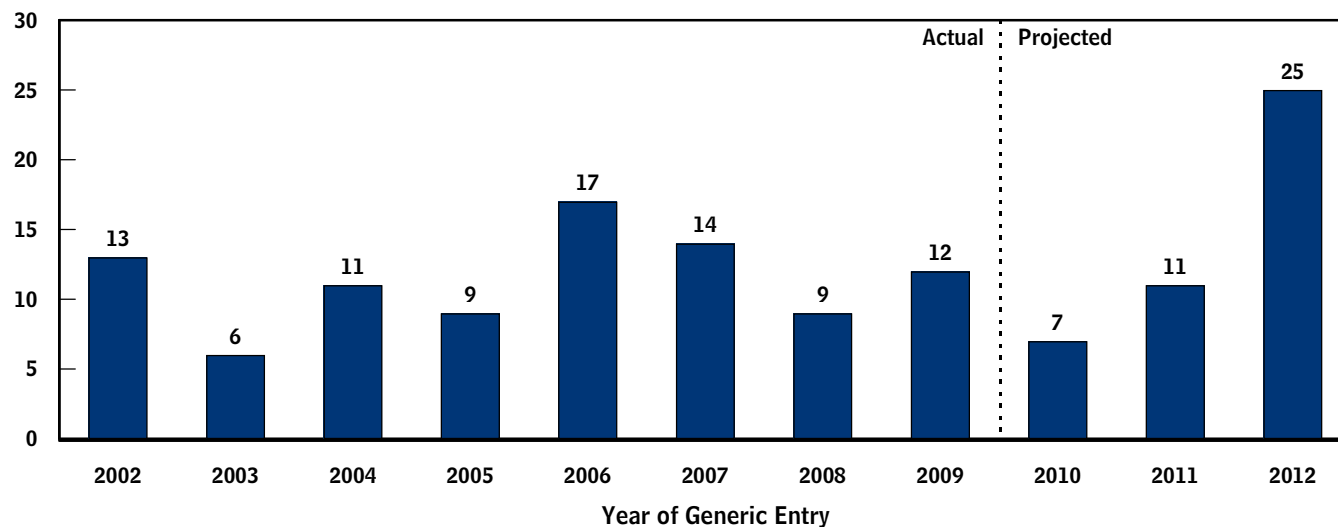
Over the past several years, more brand-name drugs have become available in generic form, and the dollar value of sales of brand-name drugs that face generic competition has increased accordingly. Brand-name drugs with U.S. retail sales totaling roughly \$21 billion in 2007, representing 11 percent of the U.S. retail market in that year, experienced first-time generic entry in 2008 and 2009 (see Figure 2). Drugs accounting for another \$43 billion in U.S. retail sales, representing a further 21 percent of the U.S. retail market in 2007, will be subject to first-time generic entry during 2010 through 2012. Within Part D, the cost of those drugs was about \$20 billion—equal to 33 percent of total payments to plans and pharmacies from the Part D program and its enrollees in 2007.

The introduction of more generic drugs increases the amount of savings that could be derived under Part D from their use. If the patterns of generic use and price differentials observed in 2007 were to continue, then 93 percent of those brand-name prescriptions would be switched to the generic version at a price 74 percent less than that of the brand-name versions. Applying those percentages to the 2007 data on drug spending yields an estimate of about \$14 billion in additional savings under Part D. That amount represents a 42 percent increase in the \$33 billion in savings estimated from generic substitution in 2007.

Because those calculations use 2007 data, they represent an estimate of the additional savings that could have

**Figure 2.****U.S. Retail Sales of Brand-Name Drugs Before First-Time Generic Entry**

(Billions of dollars)



Source: Congressional Budget Office based on Medco's *Drug Trend Reports* from 2002 through 2010.

Note: For the years from 2002 through 2008, retail sales are reported for the year before generic entry. For the years from 2009 through 2012, retail sales are reported for 2007.

accrued in 2007 if single-source drugs that will lose patent protection by 2012 had been available in generic form in 2007. Both of those savings estimates—the \$14 billion and the \$33 billion—would be higher if calculated for future years because of inflation in drug prices and the likely growth in the number of Part D enrollees and prescriptions filled. Because the price of generic drugs relative to the price of brand-name drugs declines as more manufacturers of generic drugs enter the market, the additional savings from new generic entry would also be achieved over time rather than realized immediately.

Those trends in generic drug entry also affect the estimates of how much in additional savings could be achieved either through more generic substitution or from therapeutic substitution. The calculations above assumed that 7 percent of prescriptions would have been filled with multiple-source brand-name drugs, even though generics were newly available at a price 22 percent less than the price of the brand-name drug. If all of those prescriptions were instead filled with generic drugs, about \$300 million in additional savings would be generated from generic substitution. That amount (which was also calculated using 2007 claims data and relative drug prices) represents a 33 percent increase in the \$900 million in potential savings from additional generic substitution in 2007.

A further complication is that some of the brand-name drugs experiencing first-time generic entry are in one of the seven classes for which CBO calculated savings from therapeutic substitution. The single-source drugs that will face new generic entry accounted for about \$2.5 billion of the \$4 billion in potential savings from such substitution estimated for 2007. After that generic entry occurs, savings from those drugs would be included in CBO's estimate of savings and potential additional savings from generic substitution, so potential savings from therapeutic substitution would be reduced by their contribution. In other words, the \$2.5 billion in lost savings from therapeutic substitution arises from part of the \$14 billion in additional savings that CBO estimated to stem from new generic substitution.

Then again, some of the generic entry that is expected through 2012 will create new opportunities for substitution in three additional therapeutic classes.<sup>26</sup> Although the Medicare Prescription Drug Plan Finder identifies opportunities for possible therapeutic substitutions in

26. Those additional classes are angiotensin II receptor antagonists and angiotensin II receptor antagonists/diuretic combinations (drugs in those classes treat cardiovascular diseases) and mildly/nonsedating histamine1 (H1) blocking agents/decongestants (drugs in that class treat allergies).

those three classes, they were not included in CBO's calculation of potential savings from therapeutic substitution in 2007 because they currently contain only single-source drugs. In other words, the generic drugs in those classes would be first-in-class generics and create opportunities for the type of therapeutic substitution that CBO examined.

However, the potential savings from therapeutic substitution in those three classes would be small. The potential savings associated with entry of those generic drugs was estimated as follows. Single-source brand-name drugs totaling about \$0.3 billion in prescription drug spending in 2007 would be candidates for therapeutic substitution. If enrollees' prescriptions for all of those single-source brand-name drugs were switched to the new generic drugs in their classes at a price about 70 percent less than the price of the brand-name drugs, then an additional \$0.2 billion would be saved through therapeutic substitution. On net, potential savings from therapeutic substitution in 10 therapeutic classes would decline from the \$4 billion calculated for 2007 to \$1.7 billion, or by 60 percent. Moreover, in many cases, it would be medically inappropriate to practice therapeutic substitution, which is one factor that would reduce the actual savings that could be obtained.

### New Brand-Name Drugs

The rate of introduction of new brand-name drugs is another major factor that will affect potential savings from generic drugs in the future. The introduction of new brand-name drugs can increase the utilization of single-source brand-name drugs and decrease savings from generic drugs, although the precise effect will depend on how big a share of the Part D market the new drugs can capture—and whether they shift drug utilization from existing therapies or largely establish new categories of spending. New drugs that are first in class (or breakthrough drugs) and treat a high-prevalence condition among Part D enrollees could gain a significant share of the Part D market. If enrollees switch from generic drugs to those new drugs, the opportunities for generic substitution would decline—at least until the new single-source drug loses patent protection. Moreover, if the new drug is truly superior, then opportunities for therapeutic substitution would not arise. Conversely, new drugs that enter into a crowded therapeutic class and that have little benefit over existing therapies for most people or that treat a low-prevalence condition among Part D enrollees may not gain much of a share of the Part D

market and thus may have only a limited impact on projected savings from using generic drugs.

In the near term, first-time generic entry is expected to have a bigger impact on potential savings than the introduction of new brand-name drugs because the sales of new brand-name drugs are expected to be smaller than the sales of existing brands experiencing first-time generic entry.

### Biologics

Spending under Part D on the category of drugs called biologics is expected to increase rapidly in the future. Those drugs can be particularly expensive, with prices reaching tens of thousands of dollars per patient each year. Because most biologics are injected or infused directly into the patient, they are more likely to be covered under Part B of Medicare. Consequently, biologics accounted for only about 6 percent of total prescription drug costs under Part D in 2007.<sup>27</sup> Between 2006 and 2007, however, spending on biologics under Part D grew by about 36 percent, whereas total Part D spending grew by 22 percent, according to the Medicare Payment Advisory Commission.<sup>28</sup> A higher rate of growth for Part D spending on biologics is expected to persist because of the continuing rapid increase in the price of biologics (compared with the prices of traditional drugs), greater use of existing biologics, and the large number of biologics under development.<sup>29</sup>

Provisions of the recently enacted health care legislation will partially mitigate that spending increase by creating a regulatory pathway for licensing products that are “biosimilar” to brand-name biologics. Unlike generic drugs, which contain the same active chemical ingredient as the original patented drug contains, biosimilars are similar to—but not exact copies of—much more complex molecules.

Potential savings in Part D from biosimilar drugs may be limited, however, for several reasons. In certain circum-

27. Medicare Payment Advisory Commission, *Report to the Congress: Improving Incentives in the Medicare Program* (June 2009), pp. 120–124.

28. *Ibid.*, p. 120.

29. Congressional Research Service, *Follow-On Biologics: Intellectual Property and Innovation Issues*, CRS Report for Congress RL33901 (January 6, 2010).



stances, enrollees and plans in Part D may have reduced incentives to use biosimilars. The process of designing and manufacturing biosimilars is complex and more costly than it is for traditional generic drugs, so the price discounts for biosimilars will not be as high in percentage terms as those for traditional generic drugs.<sup>30</sup> Specifically, CBO estimated that prices for biosimilars would ultimately be about 40 percent lower than prices of the original drugs—although the higher average prices for biologic products mean that the dollar differences in prices could still be quite large. The ability of plans to steer utilization toward biosimilars will also play an important role in determining the extent to which savings are realized under Part D. One potential constraint to that ability is that enrollees with low-income subsidies make up a disproportionately large share of the market for biologics under Part D. Because that group has nominal cost sharing, plans would probably need to use tools other than cost sharing (such as step therapy and prior authorization) to steer use toward biosimilars.

Another important issue is whether biosimilars will be treated in the same manner as generic drugs under Part D

as the coverage gap is filled in. In particular, CMS has not yet issued guidance on how biosimilars will be classified for purposes of coverage determination in the range of spending that (under prior law) represented the coverage gap. If biosimilars are classified in the same category as generic drugs, enrollees without low-income subsidies and their plans may have incentives to purchase brand-name biologics over biosimilars. Because plans would pay a higher share of the cost of biosimilars than of brand-name biologics in that range of spending on behalf of enrollees without low-income subsidies (see Table 1), plans would probably pay more for biosimilars than for brand-name biologics. The discount provided by manufacturers of brand-name biologics will not only reduce costs to plans and enrollees but will also be counted toward the amount of spending required to reach the catastrophic threshold (at which point coverage is borne mostly by the Part D program), whereas no discount would be required of the manufacturer of the biosimilar. Only about 2 percent of enrollees without low-income subsidies reached that threshold in 2007, however, so that incentive will probably have a limited impact on total prescription drug spending under Part D.<sup>31</sup>

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30. Congressional Budget Office, *Budget Options, Volume I: Health Care* (December 2008), pp. 126–128; and cost estimate for S. 1695, *Biologics Price Competition and Innovation Act of 2007* (June 25, 2008).

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31. For the percentage of enrollees with spending that reached the coverage gap, see Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (March 2010), p. 289.





## Appendix: Description of Data Used in This Analysis

**T**his Congressional Budget Office (CBO) analysis of prescription drug spending is based on Medicare Part D Prescription Drug Event claims data for calendar year 2007.<sup>1</sup> Plans submit the claims data to the Centers for Medicare and Medicaid Services (CMS), which uses it to calculate a portion of Medicare's payments to plans. Each record in the data indicates a filled prescription and includes information about the enrollee, plan, pharmacy, and drug product dispensed. For this analysis, the main elements of interest are the product dispensed (identified by its national drug code number), days supplied, prices of the ingredients, dispensing fee paid to the pharmacy, and sales tax.

The claims data for 2007 include about 1 billion records, or prescriptions filled. The total cost for those prescriptions was \$62.2 billion (including the prices for the ingredients, the dispensing fee, and the sales tax). For this analysis, CBO used a 1 percent sample of the claims data. The sample was constructed by first selecting a random sample of 1 percent of Part D enrollees and then selecting all the records on filled prescriptions for 2007 for those enrollees. CBO matched brand-name drugs with their chemically equivalent generic drugs in the sample using Thomson Micromedex's Red Book database. That database contains a code to identify drugs with common active ingredients, master dosage form, strength, and route of administration. It also contains information on list prices and other descriptive details on prescription and over-the-counter drugs. Using the additional information from the Red Book database, CBO was able to

categorize the drugs as generic, multiple-source brand (brands with generic versions available), or single-source brand (brands without generic versions available).

The data do not include information on rebates from drug manufacturers. But according to the 2010 report of the Board of Trustees for the Medicare program, rebates for 2007 were approximately 9.6 percent of total prescription drug costs.<sup>2</sup> Applying that factor to total recorded cost produces an estimate of \$56.2 billion for the total prescription drug cost net of rebates in 2007.

Total payments to plans and pharmacies by the Part D program and its enrollees (\$59.8 billion) exceeded the total prescription drug cost net of rebates (\$56.2 billion) by \$3.6 billion in 2007. That difference in part reflects administrative expenses and profits of plans (including the costs of managing the drug benefit, which plans may do themselves or contract out to pharmacy benefit managers). However, that difference also reflects losses that plans incur on supplemental benefits that are offset by payments under other Medicare accounts.<sup>3</sup> The Medicare Board of Trustees estimates that actual administrative expenses and profits were about \$4.3 billion in 2007 or roughly 13.5 percent of plans' benefit payments, which

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1. The claims data do not include prescription drug spending under plans that receive drug subsidies for retirees. In 2007, those subsidies totaled about \$4 billion.

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2. Medicare Board of Trustees, *2010 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (August 5, 2010), p. 185.

3. Some private plans provide Medicare Part D benefits that are integrated with other health care benefits (such as inpatient hospital stays and doctors' visits) traditionally provided under Parts A and B of Medicare. Those plans, called Medicare Advantage plans, are permitted to reduce premiums for prescription drug benefits and offer supplemental benefits using savings on Medicare payments for providing services under Parts A and B.

totaled about \$32.4 billion.<sup>4</sup> Profits and administrative expenses as a percentage of plans' benefit payments are

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4. Plans' benefit payments are for the standard benefit only. They include the Medicare Part D Program Payment for the standard benefit (\$26.1 billion), enrollees' premiums for the standard benefit (\$4.0 billion), and low-income subsidies for premiums (\$2.3 billion). They do not include payments for supplemental benefits and low-income subsidies for cost sharing (deductibles, coinsurance, and copayments).

expected to decline slowly through 2019 because increases in prescription drug spending under Part D are estimated to be larger than increases in employee wages and the other input costs that affect plans' administrative expenses.<sup>5</sup>

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5. See Medicare Board of Trustees, *2010 Annual Report*, p. 185, for projections of plans' administrative expenses and profits.