Congressional CBO Budget Office
Summary

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 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.