Why GAO Did This Study

The Centers for Medicare & Medicaid Services (CMS) allows Part D plans to utilize different tiers with different levels of cost sharing as a way of managing drug utilization and spending. One such tier, the specialty tier, is designed for high-cost drugs whose prices exceed a certain threshold set by CMS. Beneficiaries who use these drugs typically face higher out-of-pocket costs than beneficiaries who use only lower-cost drugs.

This testimony is based on GAO’s January 2010 report entitled Medicare Part D: Spending, Beneficiary Out-of-Pocket Costs, and Efforts to Obtain Price Concessions for Certain High-Cost Drugs (GAO-10-242) in which GAO examined, among other things, (1) Part D spending on these drugs in 2007, the most recent year for which claims data were available; (2) how different cost-sharing structures could be expected to affect beneficiary out-of-pocket costs; (3) how negotiated drug prices could be expected to affect beneficiary out-of-pocket costs; and (4) information Part D plan sponsors reported on their ability to negotiate price concessions. For the second and third of these objectives, this testimony focuses on out-of-pocket costs for beneficiaries responsible for paying the full cost-sharing amounts required by their plans. Variations in negotiated prices can occur between plans, across plans for the same drug, and from year to year. For example, the average negotiated price for the cancer drug Gleevec across our sample of plans increased by 46 percent between 2006 and 2009, from about $31,200 per year to about $45,500 per year. Correspondingly, the average out-of-pocket cost for a beneficiary taking Gleevec for the entire year could have been expected to rise from about $4,900 in 2006 to more than $6,300 in 2009.

Plan sponsors reported having little leverage to negotiate price concessions from manufacturers for most specialty tier-eligible drugs. One reason for this limited leverage was that many of these drugs have few competitors on the market. Plan sponsors reported that they were more often able to negotiate price concessions for drugs with more competitors on the market—such as for drugs used to treat rheumatoid arthritis. Two additional reasons cited for limited negotiating leverage were CMS requirements that plans include all or most drugs from certain therapeutic classes on their formularies, limiting sponsors’ ability to exclude drugs from their formularies in favor of competing drugs; and that the relatively limited share of total prescription drug utilization among Part D beneficiaries for some specialty tier-eligible drugs was insufficient to entice manufacturers to offer price concessions.

CMS provided GAO with comments on a draft of the January 2010 report. CMS agreed with portions of GAO’s findings and suggested additional information for GAO to include in the report, which GAO incorporated as appropriate.

What GAO Found

High-cost drugs eligible for a specialty tier commonly include immunosuppressant drugs, those used to treat cancer, and antiviral drugs. Specialty tier-eligible drugs accounted for 10 percent, or $5.6 billion, of the $54.4 billion in total prescription drug spending under Medicare Part D plans in 2007. Medicare beneficiaries who received a low-income subsidy (LIS) accounted for most of the spending on specialty tier-eligible drugs—$4.0 billion, or 70 percent of the total. Among all beneficiaries who used at least one specialty tier-eligible drug in 2007, 55 percent reached the catastrophic coverage threshold, after which Medicare pays at least 80 percent of all drug costs. In contrast, only 8 percent of all Part D beneficiaries who filed claims but did not use any specialty tier-eligible drugs reached this threshold in 2007.

Most beneficiaries are responsible for paying the full cost-sharing amounts required by their plans. For such beneficiaries who use a given specialty tier-eligible drug, different cost-sharing structures result in varying out-of-pocket costs only until they reach the catastrophic coverage threshold, which 31 percent of these beneficiaries did in 2007. After that point, beneficiaries’ annual out-of-pocket costs for a given drug are likely to be similar regardless of their plans’ cost-sharing structures.

Variations in negotiated drug prices can also affect out-of-pocket costs for beneficiaries who are responsible for paying the full cost-sharing amounts required by their plans. Variations in negotiated prices can occur between drugs, across plans for the same drug, and from year to year. For example, the average negotiated price for the cancer drug Gleevec across our sample of plans increased by 46 percent between 2006 and 2009, from about $31,200 per year to about $45,500 per year. Correspondingly, the average out-of-pocket cost for a beneficiary taking Gleevec for the entire year could have been expected to rise from about $4,900 in 2006 to more than $6,300 in 2009.

Plan sponsors reported having little leverage to negotiate price concessions from manufacturers for most specialty tier-eligible drugs. One reason for this limited leverage was that many of these drugs have few competitors on the market. Plan sponsors reported that they were more often able to negotiate price concessions for drugs with more competitors on the market—such as for drugs used to treat rheumatoid arthritis. Two additional reasons cited for limited negotiating leverage were CMS requirements that plans include all or most drugs from certain therapeutic classes on their formularies, limiting sponsors’ ability to exclude drugs from their formularies in favor of competing drugs; and that the relatively limited share of total prescription drug utilization among Part D beneficiaries for some specialty tier-eligible drugs was insufficient to entice manufacturers to offer price concessions.

CMS provided GAO with comments on a draft of the January 2010 report. CMS agreed with portions of GAO’s findings and suggested additional information for GAO to include in the report, which GAO incorporated as appropriate.