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MEDICARE PART D

Spending, Beneficiary Out-of-Pocket Costs, and Efforts to Obtain Price Concessions for Certain High-Cost Drugs

Statement of John E. Dicken
Director, Health Care

March 17, 2010

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Highlights

Highlights of GAO-10-529T, a testimony before the Special Committee on Aging, U.S. Senate

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 Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier* (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. GAO examined CMS data and interviewed officials from CMS and 8 of the 11 largest plan sponsors, based on enrollment in 2008. Seven of the 11 plan sponsors provided price concession data for a sample of 20 drugs for 2006 through 2008.

View GAO-10-529T or key components.
For more information, contact John E. Dicken at (202) 512-7114 or DickenJ@gao.gov.

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.

Mr. Chairman and Members of the Committee:

I am pleased to be here today to discuss high-cost drugs covered under Medicare Part D and to provide highlights from our January 2010 report entitled *Medicare Part D: Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier*.[1] Medicare Part D is the outpatient prescription drug benefit offered by Medicare, the federal health insurance program which serves about 45 million elderly and disabled individuals. Some drugs covered by Part D have particularly high costs—sometimes exceeding tens of thousands of dollars per year—and beneficiaries who take these drugs often face high annual out-of-pocket costs.

Under Part D, coverage and beneficiary cost sharing can vary. Medicare beneficiaries obtain Part D drug coverage by choosing from multiple competing plans offered by plan sponsors—often private insurers—that contract with the Centers for Medicare & Medicaid Services (CMS) in order to offer the prescription drug benefit. As of February 2010, CMS reported that 27.6 million beneficiaries were enrolled in Part D plans. Part D plan sponsors can offer a range of plans with either a defined standard benefit or an actuarially equivalent alternative, or plans with enhanced benefits. Plans can vary in the coverage provided, monthly premiums, and cost-sharing structure such as copayments and coinsurance.[2] Most Part D beneficiaries—approximately 18 million—are responsible for paying the full premium and cost-sharing amounts required by their plans. Part D provides premium and cost-sharing assistance through its low-income subsidy (LIS) for other beneficiaries who meet certain income and asset requirements.

Plan sponsors can assign covered drugs to distinct tiers, such as separate tiers for generic and brand-name drugs. These tiers often have increasing levels of cost sharing in order to encourage beneficiaries to utilize less costly drugs such as generics. CMS also allows Part D plans to establish a "specialty tier" for high-cost drugs when the total cost for a drug—as determined through negotiations between the plan and pharmacies—

[1]GAO, *Medicare Part D: Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier*, GAO-10-242 (Washington, D.C.: Jan. 29, 2010).

[2]A copayment is usually a fixed dollar amount paid by the beneficiary, while coinsurance is a percentage of the cost.

exceeds a certain threshold, set by CMS at $500 per month for 2007 and $600 per month for 2008 through 2010. Drugs eligible to be placed on specialty tiers are among the most expensive drugs on the market. They are used by a small proportion of beneficiaries and commonly include immunosuppressant drugs, those used to treat cancer, and antiviral drugs. Plan sponsors may be able to manage spending on these high-cost drugs by negotiating price concessions with manufacturers or price discounts with pharmacies.[3]

My statement today is based upon our January 2010 report, in which we examined, among other things, (1) spending under Medicare Part D on specialty tier-eligible drugs covered in 2007, the most recent year for which claims data were available when we conducted our study; (2) how the different cost-sharing structures used by Part D plans for specialty tier-eligible drugs could be expected to affect beneficiary out-of-pocket costs; (3) how prices negotiated with pharmacies for specialty tier-eligible drugs could be expected to affect beneficiary out-of-pocket costs; and (4) the ability of Part D plans to negotiate price concessions from manufacturers for specialty tier-eligible drugs. For the second and third of these objectives, my statement today focuses primarily on out-of-pocket costs for most beneficiaries—those who are responsible for paying the full cost-sharing amounts required by their plans. Details on out-of-pocket costs for LIS beneficiaries, which are subsidized by Medicare, can be found in our January 2010 report.

To do the work for our report, we examined CMS's Prescription Drug Event (PDE) claims data from 2007 for Medicare Advantage prescription drug (MA-PD) plans and stand-alone prescription drug plans (PDP) to determine spending on drugs eligible to be placed on a Part D plan's specialty tier. For our purposes, we considered specialty tier-eligible drugs to be all drugs with claims reimbursed under Part D with a median negotiated cost of at least $500 for a 30-day supply (i.e., where at least half of the claims for these drugs in 2007 met or exceeded the CMS cost threshold of $500 per month). We analyzed the effect of typical cost-sharing structures on beneficiary out-of-pocket costs. We also chose a judgmental sample of 20 specialty tier-eligible drugs and a sample of 36 high-enrollment MA-PD and PDP plans from six counties based on

[3]Sponsors must pass price concessions on to the program. See the Social Security Act §§ 1860 D-2(d)(1)(A), -15(b)(2), and -15(e)(1)(B) (as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [MMA]) (codified at 42 U.S.C. §§ 1395w-102(d)(1)(A), -115(b)(2), and -115(e)(1)(B)).

enrollment as of March 2008. We used CMS negotiated price data[4] and CMS estimates of beneficiary out-of-pocket costs for our sample of drugs in 35 of the 36 selected plans[5] to analyze how negotiated drug prices could be expected to affect beneficiary out-of-pocket costs from 2006 through 2009. The results of this analysis cannot be generalized beyond our judgmental sample of drugs and selected plans. We conducted interviews with representatives from 8 of the 11 largest MA-PD and PDP plan sponsors based on 2008 enrollment data from CMS. In addition, 7 of the plan sponsors we interviewed provided price concession data for our sample of 20 specialty tier-eligible drugs for 2006 through 2008. These 7 plan sponsors represented 51 percent of all MA-PD enrollment and 67 percent of all PDP enrollment in 2008. We determined that the data we used for our report were sufficiently reliable for our purposes. We conducted the work for our report from March 2009 through December 2009 in accordance with all sections of GAO's quality assurance framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions in this product. A detailed explanation of our methodology is included in our January 2010 report.

Background

Under the defined standard benefit in 2009, beneficiaries subject to full cost-sharing amounts paid out-of-pocket costs during the initial coverage period that included a deductible equal to the first $295 in drug costs, followed by 25 percent coinsurance for all drugs until total drug costs reached $2,700, with beneficiary out-of-pocket costs accounting for $896.25 of that total. (See fig. 1.) This initial coverage period is followed by a coverage gap—the so-called doughnut hole—in which these

[4]Negotiated drug prices are prices negotiated between pharmacies and plan sponsors for drugs dispensed by a pharmacy to plan beneficiaries and are reported by plan sponsors to CMS. CMS negotiated price data, which reflect average prices reported by plans across pharmacies available to beneficiaries, can be used only to estimate average beneficiary out-of-pocket costs, and may not reflect actual out-of-pocket costs paid by beneficiaries. The latter are influenced by factors—such as the extent of price concessions negotiated between plans and pharmacies—that vary by pharmacy and region.

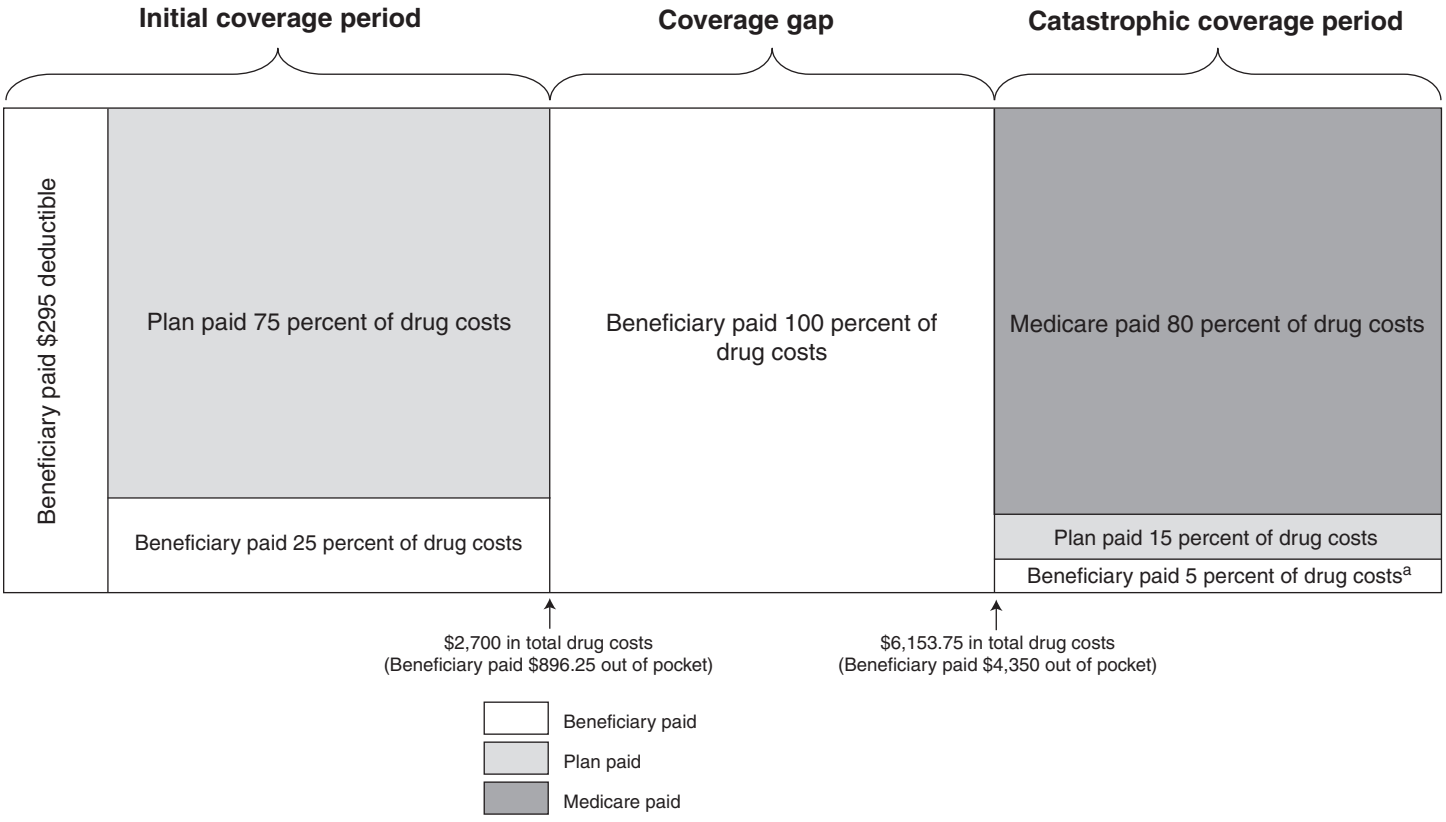
[5]CMS was unable to provide negotiated drug price data and estimated out-of-pocket costs for all 4 years—2006 through 2009—for one plan in our sample. Therefore, we excluded this plan from our analyses.

beneficiaries paid 100 percent of their drug costs. In 2009, the coverage gap lasted until total drug costs—including the costs accrued during the initial coverage period—reached $6,153.75, with beneficiary out-of-pocket drug costs accounting for $4,350 of that total. This point is referred to as the catastrophic coverage threshold.[6] After reaching the catastrophic coverage threshold, beneficiaries taking a specialty tier-eligible drug paid 5 percent of total drug costs for each prescription for the remainder of the year.[7]

[6]In designing an actuarially equivalent alternative plan, plan sponsors must maintain the catastrophic coverage threshold set by CMS pursuant to law ($4,350 in 2009). See the Social Security Act §1860D-2(b)(4)(B) (as added by the MMA) (codified at 42 U.S.C. §1395w-102(b)(4)(B)).

[7]For 2010, the standard benefit amounts set by CMS are as follows: a $310 deductible, a $2,830 initial coverage limit, and a catastrophic coverage threshold of $4,550.

Figure 1: Medicare Part D Cost-Sharing Structure for Specialty Tier-Eligible Drugs under the Defined Standard Benefit, 2009



Source: GAO analysis of CMS data.

Note: LIS beneficiaries paid lower amounts in all phases of the benefit, while Medicare paid the remainder of beneficiaries' out-of-pocket costs.

[a]Because of the high cost of specialty tier-eligible drugs, the beneficiary always paid 5 percent of drug costs during the catastrophic coverage period.

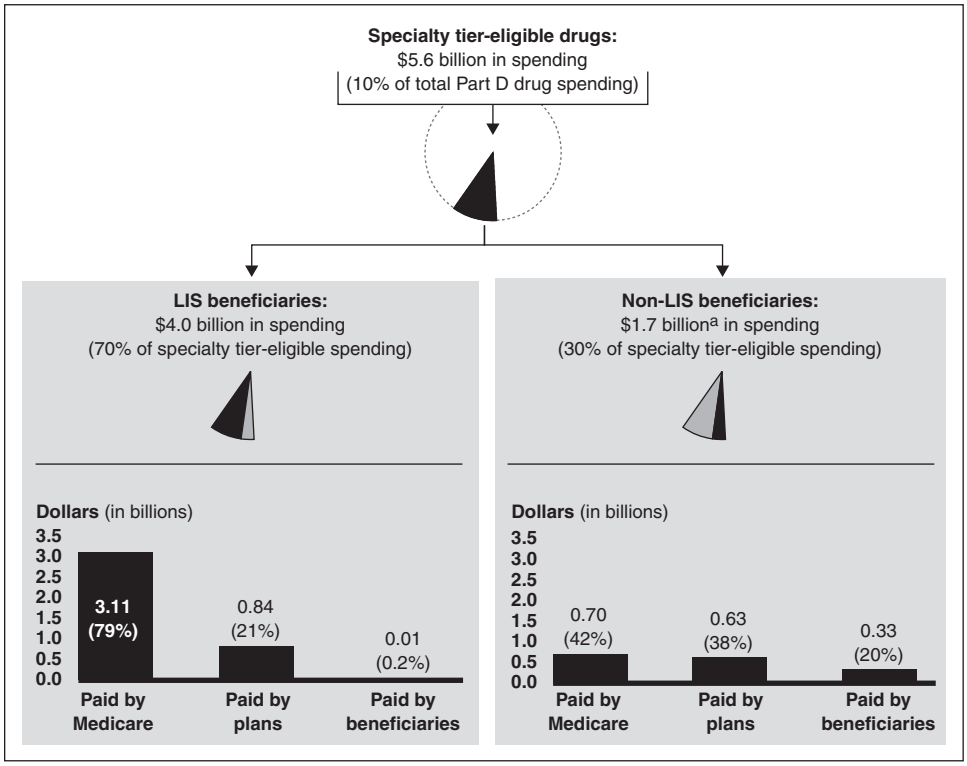
In addition to cost sharing for prescription drugs, many Part D plans also charge a monthly premium. In 2009, premiums across all Part D plans averaged about $31 per month, an increase of 24 percent from 2008.[8] Beneficiaries are responsible for paying these premiums except in the case of LIS beneficiaries, whose premiums are subsidized by Medicare.

[8]"A Status Report on Part D for 2009," *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: Medicare Payment Advisory Commission [MedPAC], March 2009), http://www.medpac.gov/document_search.cfm (accessed Aug. 13, 2009).

In 2007, Specialty Tier-Eligible Drugs Accounted for 10 Percent of Part D Spending

We found that specialty tier-eligible drugs accounted for about 10 percent, or $5.6 billion, of the $54.4 billion in total prescription drug spending under Part D MA-PD and PDP plans in 2007.[9] Prescriptions for LIS beneficiaries accounted for about 70 percent, or about $4.0 billion, of the $5.6 billion spent on specialty tier-eligible drugs under MA-PD and PDP plans that year. (See fig. 2.) The fact that spending on specialty tier-eligible drugs in 2007 was largely accounted for by LIS beneficiaries is noteworthy because their cost sharing is largely paid by Medicare.

Figure 2: Spending on Specialty Tier-Eligible Drugs under Part D MA-PD and PDP Plans, 2007



Source: GAO analysis of CMS data.

[a]Totals do not add to $5.6 billion due to rounding.

[9]These amounts include spending by Medicare, the plans, and beneficiaries.

While only 8 percent of Part D beneficiaries in MA-PD and PDP plans who filed claims but did not use any specialty tier-eligible drugs reached the catastrophic coverage threshold of the Part D benefit in 2007, 55 percent of beneficiaries who used at least one specialty tier-eligible drug reached the threshold. Specifically, among those beneficiaries who used at least one specialty tier-eligible drug in 2007, 31 percent of beneficiaries responsible for paying the full cost sharing required by their plans and 67 percent of beneficiaries whose costs were subsidized by Medicare through the LIS reached the catastrophic coverage threshold. Most (62 percent) of the $5.6 billion in total Part D spending on specialty tier-eligible drugs under MA-PD and PDP plans occurred after beneficiaries reached the catastrophic coverage phase of the Part D benefit.

Differences in Plans' Cost-Sharing Structures Result in Out-of-Pocket Costs for Most Beneficiaries That Vary Initially and Then Become Similar

For most beneficiaries—those who are responsible for paying the full cost-sharing amounts required by their plans—who use a given specialty tier-eligible drug, different cost-sharing structures can be expected to result in varying out-of-pocket costs during the benefit's initial coverage period.[10] However, as long as beneficiaries reach the catastrophic coverage threshold in a calendar year—as 31 percent of beneficiaries who used at least one specialty tier-eligible drug and who were responsible for the full cost-sharing amounts did in 2007—their annual out-of-pocket costs for that drug are likely to be similar regardless of their plans' cost-sharing structures.

During the initial coverage period, the estimated out-of-pocket costs for these beneficiaries for a given specialty tier-eligible drug are likely to vary, because some Part D plans may place the drug on a tier with coinsurance while other plans may require a flat copayment for the drug. For example, estimated 2009 out-of-pocket costs during the initial coverage period, excluding any deductibles, for a drug with a monthly negotiated price of $1,100 would range from $25 per month for a plan with a flat $25 monthly copayment to $363 per month for a plan with a 33 percent coinsurance rate.[11]

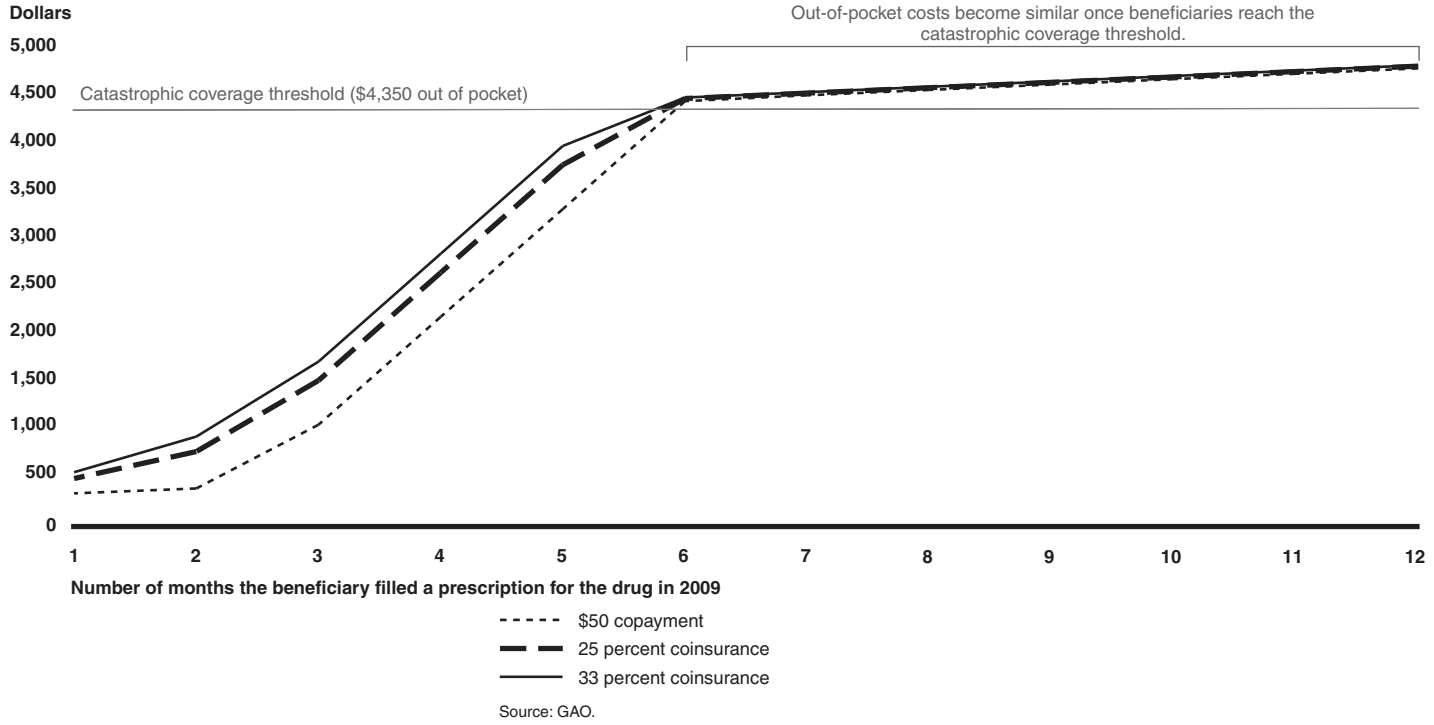
[10]LIS beneficiaries' out-of-pocket costs for all drugs, including specialty tier-eligible drugs, are not significantly affected by different plans' cost-sharing structures because Medicare has established fixed cost-sharing levels for all LIS beneficiaries, regardless of the plans in which they are enrolled.

[11]$1,100 per month was the utilization-weighted average of the median negotiated price of all specialty tier-eligible drugs in 2007 based on PDE claims data.

However, even if beneficiaries pay different out-of-pocket costs during the initial coverage period, their out-of-pocket costs become similar due to the coverage gap and the fixed catastrophic coverage threshold ($4,350 in out-of-pocket costs in 2009). (See fig. 3.) There are several reasons for this. First, beneficiaries taking equally priced drugs will reach the coverage gap at the same time—even with different cost-sharing structures—because entry into the coverage gap is based on total drug costs paid by the beneficiary and the plan, rather than on out-of-pocket costs paid by the beneficiary. Since specialty tier-eligible drugs have high total drug costs, beneficiaries will typically reach the coverage gap within 3 months in the same calendar year. Second, during the coverage gap, beneficiaries typically pay 100 percent of their total drug costs until they reach the catastrophic coverage threshold. This threshold ($4,350 in out-of-pocket costs) includes costs paid by the beneficiary during the initial coverage period. Therefore, beneficiaries who paid higher out-of-pocket costs in the initial coverage period had less to pay in the coverage gap before they reached the threshold. Conversely, beneficiaries who paid lower out-of-pocket costs in the initial coverage period had more to pay in the coverage gap before they reached the same threshold of $4,350 in out-of-pocket costs. Third, after reaching the threshold, beneficiaries' out-of-pocket costs become similar because they typically pay 5 percent of the drug's negotiated price for the remainder of the calendar year.[12]

[12]While not common, some plan sponsors offer MA-PD plans with lower cost sharing than the usual 100 percent during the coverage gap or the usual 5 percent during the catastrophic coverage period. In these rare cases, beneficiaries would have lower out-of-pocket costs for specialty tier-eligible drugs over the course of the calendar year.

Figure 3: Cumulative Beneficiary Out-of-Pocket Costs under Different Cost-Sharing Structures for a Drug with a Negotiated Price of $1,100 per Month, for Beneficiaries Responsible for Full Cost-Sharing Amounts



Source: GAO.

Note: All scenarios include a $295 annual deductible paid by the beneficiary, $2,700 initial coverage limit, and $4,350 catastrophic coverage threshold.

Variations in Negotiated Drug Prices Affect Out-of-Pocket Costs for Most Beneficiaries

For most beneficiaries—those who are responsible for paying the full cost-sharing amounts required by their plans—variations in negotiated drug prices affect out-of-pocket costs during the initial coverage phase if their plans require them to pay coinsurance.[13] All 35 of our selected plans required beneficiaries to pay coinsurance in 2009 for at least some of the 20 specialty tier-eligible drugs in our sample. Additionally, negotiated drug prices will affect these beneficiaries' out-of-pocket costs during the coverage gap and the catastrophic coverage phase because beneficiaries generally pay the entire negotiated price of a drug during the coverage gap and pay 5 percent of a drug's negotiated price during the catastrophic

[13]Out-of-pocket costs for LIS beneficiaries are generally not affected by variations in negotiated drug prices because most LIS beneficiaries pay a flat monthly copayment for all drugs regardless of the drug's price.

coverage phase. As the following examples illustrate, there are variations in negotiated prices between drugs, across plans for the same drug, and from year to year.

- **Variations between drugs**: In 2009—across our sample of 35 plans—beneficiaries who took the cancer drug Gleevec for the entire year could have been expected to pay about $6,300 out of pocket because Gleevec had an average negotiated price of about $45,500 per year, while beneficiaries could have been expected to pay about $10,500 out of pocket over the entire year if they took the Gaucher disease drug Zavesca, which had an average negotiated price of about $130,000 per year.[14]

- **Variations across plans**: In 2009, the negotiated price for the human immunodeficiency virus (HIV) drug Truvada varied from about $10,900 to about $11,400 per year across different plans with a 33 percent coinsurance rate, resulting in out-of-pocket costs that could be expected to range from about $4,600 to $4,850 for beneficiaries taking the drug over the entire year.

- **Variations over time**: Since 2006, average negotiated prices for the specialty tier-eligible drugs in our sample have risen across our sample of plans; the increases averaged 36 percent over the 3-year period.[15] These increases, in turn, led to higher estimated beneficiary out-of-pocket costs for these drugs in 2009 compared to 2006. For example, the average negotiated price for a 1-year supply of Gleevec across our sample of plans increased by 46 percent, from about $31,200 in 2006 to about $45,500 in 2009. Correspondingly, the average out-of-pocket cost for a beneficiary taking Gleevec for an entire year could have been expected to rise from about $4,900 in 2006 to more than $6,300 in 2009.

[14]Values reported are averages in 2009 across the 35 selected plans used in our analysis.

[15]We calculated average negotiated drug prices separately for 2006 and 2009 across all plans that covered a given drug for each year and then compared the two average prices to determine the percent increase. CMS did not provide negotiated prices or estimated out-of-pocket costs for four drugs in our sample—Aranesp, Intron-A, Kaletra, and Letairis—for 2006. Therefore, these drugs are excluded from this calculation.

Plan Sponsors Report Three Main Reasons Why They Have a Limited Ability to Negotiate Price Concessions for Specialty Tier-Eligible Drugs

The eight Part D plan sponsors we interviewed told us that they have little leverage in negotiating price concessions for most specialty tier-eligible drugs. Additionally, all seven of the plan sponsors we surveyed reported that they were unable to obtain price concessions from manufacturers on 8 of the 20 specialty tier-eligible drugs in our sample between 2006 and 2008.[16] For most of the remaining 12 drugs in our sample, plan sponsors who were able to negotiate price concessions reported that they were only able to obtain price concessions that averaged 10 percent or less, when weighted by utilization, between 2006 and 2008. (See app. I for an excerpt of the price concession data presented in our January 2010 report.)

The plan sponsors we interviewed cited three main reasons why they have typically had a limited ability to negotiate price concessions for specialty tier-eligible drugs. First, they stated that pharmaceutical manufacturers have little incentive to offer price concessions when a given drug has few competitors on the market, as is the case for drugs used to treat cancer. For Gleevec and Tarceva, two drugs in our sample that are used to treat certain types of cancer, plan sponsors reported that they were not able to negotiate any price concessions between 2006 and 2008. In contrast, plan sponsors told us that they were more often able to negotiate price concessions for drugs in classes where there are more competing drugs on the market—such as for drugs used to treat rheumatoid arthritis, multiple sclerosis, and anemia. The anemia drug Procrit was the only drug in our sample for which all of the plan sponsors we surveyed reported that they were able to obtain price concessions each year between 2006 and 2008.

Second, plan sponsors told us that even when there are competing drugs, CMS may require plans to include all or most drugs in a therapeutic class on their formularies, and such requirements limit the leverage a plan sponsor has when negotiating price concessions. When negotiating price concessions with pharmaceutical manufacturers, the ability to exclude a drug from a plan's formulary in favor of a therapeutic alternative is often a significant source of leverage available to a plan sponsor. However, many specialty tier-eligible drugs belong to one of the six classes of clinical concern for which CMS requires Part D plan sponsors to include all or substantially all drugs on their formularies, eliminating formulary

[16]One of the plan sponsors we interviewed declined to provide price concession data through our survey.

exclusion as a source of negotiating leverage.[17] We found that specialty tier-eligible drugs were more than twice as likely to be in one of the six classes of clinical concern compared with lower-cost drugs in 2009.[18] Additionally, among the 8 drugs in our sample of 20 specialty tier-eligible drugs for which the plan sponsors we surveyed reported they were unable to obtain price concessions between 2006 and 2008, 4 drugs were in one of the six classes of clinical concern. Plan sponsors are also required to include at least two therapeutic alternatives from each of the other therapeutic classes on their formularies.

Third, plan sponsors told us that they have limited ability to negotiate price concessions for certain specialty tier-eligible drugs because they account for a relatively limited share of total prescription drug utilization among Part D beneficiaries. For some drugs in our sample, such as Zavesca, a drug used to treat a rare enzyme disorder called Gaucher disease, the plan sponsors we surveyed had very few beneficiary claims between 2006 and 2008. None of the plan sponsors we surveyed reported price concessions for this drug during this period. Plan sponsors told us that utilization volume is usually a source of leverage when negotiating price concessions with manufacturers for Part D drugs. For some specialty tier-eligible drugs like Zavesca, however, the total number of individuals using the drug may be so limited that plans are not able to enroll a significant enough share of the total users to entice the manufacturer to offer a price concession.

Agency Comments and Our Evaluation

The Department of Health and Human Services (HHS) provided us with CMS's written comments on a draft version of our January 2010 report. CMS agreed with portions of our findings and suggested additional information for us to include in our report. We also provided excerpts of the draft report to the eight plan sponsors who were interviewed for this

[17]A therapeutic class or category of drugs is generally based on an indication approved by the Food and Drug Administration. Part D sponsor formularies must include all or substantially all drugs in the following six classes of clinical concern as identified by CMS: immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic. Examples of other therapeutic classes include analgesics, blood glucose regulators, cardiovascular agents, dermatological agents, respiratory tract agents, and sedatives.

[18]This analysis was conducted by comparing specialty tier-eligible and nonspecialty tier-eligible drugs at the drug (ingredient) level with a list of drugs in the six classes of clinical concern provided by CMS.

study and they provided technical comments. We incorporated comments from CMS and the plan sponsors as appropriate in our January 2010 report.

Mr. Chairman, this completes my prepared remarks. I would be happy to respond to any questions you or other Members of the Committee may have at this time.

GAO Contact and Staff Acknowledgements

For further information about this statement, please contact John E. Dicken at (202) 512-7114 or DickenJ@gao.gov.

Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Key contributors to this statement in addition to the contact listed above were Will Simerl, Assistant Director; Krister Friday; Karen Howard; Gay Hee Lee; and Alexis MacDonald.

Appendix I: Comparison of Price Concessions Negotiated by Seven Plan Sponsors for a Sample of 20 Drugs in 2008

Drugs (including strength and dosage form), by indication	Number of plan sponsors that obtained price concessions	Average negotiated price per 30-day supply, before price concessions, weighted by utilization (dollars)	Average negotiated price per 30-day supply, after price concessions, weighted by utilization (dollars)
Multiple sclerosis			
Glatiramer acetate (Copaxone) 20 mg/ml injection	7	1,867	1,732
Interferon beta-1a (Avonex) 30 mcg intramuscular injection	5	1,935	1,884
Inflammatory conditions (e.g., rheumatoid arthritis, psoriasis, Crohn's disease)[a]			
Adalimumab (Humira) 40 mg/0.8 ml injection	7	1,600	1,469
Anakinra (Kineret) 100 mg injection	–[b]	1,424	1,423
Etanercept (Enbrel) 50 mg/ml injection	6	1,527	1,470
Human immunodeficiency virus (HIV)			
Atazanavir sulfate (Reyataz) 150 mg tablet	6	853	810
Emtricitabine and tenofovir disoproxil fumarate (Truvada) 200 mg/300 mg tablet	0	881	881
Lamivudine and zidovudine (Combivir) 150 mg/300 mg tablet	6	741	714
Lopinavir and ritonavir (Kaletra) 200 mg/50 mg tablet	0	745	745
Cancer			
Erlotinib (Tarceva)[c] 150 mg tablet	0	3,393	3,393
Imatinib mesylate (Gleevec) 400 mg tablet	0	3,389	3,389
Hepatitis C			
Interferon alfa-2b (Intron-A) 3 million IU injection	0	580	580
Peginterferon alfa 2a (Pegasys)[c] 180 mg/0.5 ml injection	6	1,817	1,561

Drugs (including strength and dosage form), by indication	Number of plan sponsors that obtained price concessions	Average negotiated price per 30-day supply, before price concessions, weighted by utilization (dollars)	Average negotiated price per 30-day supply, after price concessions, weighted by utilization (dollars)
Anemia			
Darbepoetin alfa (Aranesp) 100 mcg/0.5 ml injection	4	1,128	994
Epoetin alfa (Procrit) 40,000 units/ml injection	7	1,593	1,420
Enzyme disorders (e.g., Gaucher disease)			
Miglustat (Zavesca) 100 mg capsule	0	8,344	8,344
Pulmonary arterial hypertension			
Ambrisentan (Letairis) 10 mg tablet	0	4,416	4,416
Bosentan (Tracleer) 125 mg tablet	0	4,423	4,423
Other (selected based on high utilization)			
Mycophenolate mofetil (CellCept)—immune suppressant 500 mg tablet	7	681	652
Teriparatide (Forteo)[c]—osteoporosis 250 mcg/ml injection	4	748	641

Source: GAO analysis of price concessions data provided by seven plan sponsors GAO surveyed.

[a]These three distinct diseases (rheumatoid arthritis, psoriasis, and Crohn's disease) may be treated using some of the same drugs. We selected three of those drugs for our sample.

[b]The total number of plan sponsors who reported receiving price concessions for this drug was too small to allow us to report this value while maintaining confidentiality.

[c]One of the seven plan sponsors we surveyed did not submit any data for this drug. Therefore, values listed for this drug are based on data submitted by six plan sponsors, rather than seven plan sponsors.

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