United States Government Accountability Office

GAO

Report to Congressional Requesters

September 2012

MEDICARE PART D COVERAGE GAP

Discount Program Effects and Brand-Name Drug Price Trends

To access this report electronically, scan this QR Code.

Don't have a QR code reader? Several are available for free online.

G A O

Accountability * Integrity * Reliability

GAO-12-914

September 2012

MEDICARE PART D COVERAGE GAP

Discount Program Effects and Brand-Name Drug Price Trends

GAO Highlights

Accountability * Integrity * Reliability

Highlights of GAO-12-914, a report to congressional requesters

Why GAO Did This Study

The Patient Protection and Affordable Care Act of 2010 established the Discount Program to help Medicare Part D beneficiaries with their prescription drug costs while in the coverage gap, which occurs between the initial and catastrophic coverage periods where Medicare helps pay for drug costs. Until the Discount Program began in 2011, beneficiaries in the coverage gap paid 100 percent of drug costs. The Discount Program required manufacturers to provide a 50 percent discount on the price of brand-name drugs for beneficiaries in the gap.

GAO was asked to describe (1) CMS's oversight of the Discount Program; (2) perspectives of plan sponsors, manufacturers, and PBMs on effects of the Discount Program; and (3) how prices for brand-name drugs used by beneficiaries in the coverage gap and by those who did not reach the gap changed before and after the start of the Discount Program. To describe CMS's oversight, GAO reviewed CMS documents and interviewed CMS officials. To describe perspectives on the effects of the Discount Program, GAO interviewed the 7 largest Part D plan sponsors based on enrollment data, 8 of 10 manufacturers of brand-name drugs with the highest expenditures in the gap, and 3 PBMs who contracted with sponsors GAO interviewed. To describe price changes, GAO used CMS Part D data from 2007 to 2011 to track prices for high-expenditure brand-name drugs used by those in and those who did not reach the gap. GAO compared prices for the two baskets because drugs used by those in the gap may be more susceptible to price increases since manufacturers must provide the discount for these drugs.

View GAO-12-914. For more information, contact John Dicken at (202) 512-7114 or DickenJ@gao.gov.

What GAO Found

As part of Medicare's Part D Coverage Gap Discount Program (Discount Program), the Centers for Medicare & Medicaid Services (CMS), located within the Department of Health and Human Services (HHS), oversees the provision of discounts by plan sponsors to eligible beneficiaries when they purchase brand-name drugs and monitors that discounts are paid for by drug manufacturers. CMS checks prescription drug data to verify that sponsors provide accurate discounts at the point-of-sale to eligible beneficiaries in the coverage gap. These checks include verifying whether a beneficiary has reached the coverage gap and that the plan sponsor has calculated the discount amount correctly. CMS also tracks that manufacturers pay plan sponsors for the discounts sponsors have provided to beneficiaries and has implemented a dispute resolution process for manufacturers disputing discount payment amounts. CMS also performs other activities such as monitoring beneficiary complaints related to the program.

The plan sponsors, pharmacy benefit managers (PBM) that negotiate on behalf of plan sponsors, and drug manufacturers GAO interviewed had different perspectives on aspects of the drug pricing and plan design effects of the Discount Program. Most sponsors and PBMs believed the Discount Program may have been a contributing factor in the rising prices of some brand-name drugs by some manufacturers. However, most manufacturers did not believe the Discount Program affected drug prices they negotiated with sponsors and PBMs. The PBMs we interviewed also told us they observed that some manufacturers decreased the amount of rebates for the brand-name drugs they offered, which they believe occurred as a result of the Discount Program. In comparison, most of the plan sponsors did not observe manufacturers decreasing rebate amounts and most manufacturers reported no effects on their rebate negotiations as a result of the Discount Program. Most sponsors and PBMs told GAO that the Discount Program did not affect Part D plan formularies, plan benefit designs, or utilization management practices.

GAO found that the prices for high-expenditure brand-name drugs used by beneficiaries in the coverage gap and by those who did not reach the gap in 2011 increased at a similar rate before and after the Discount Program was implemented in January 2011. Specifically, from January 2007 to December 2010, before the Discount Program began, the median price for the basket of 77 brand-name drugs (weighted by the utilization of each drug) used by beneficiaries in the coverage gap increased 36.2 percent. During the same period, the median price for the basket of 78 brand-name drugs used by beneficiaries who did not reach the coverage gap increased 35.2 percent. From December 2010 through December 2011, the first year with the Discount Program, the median price for the two baskets increased equally by about 13 percent, the greatest increase in median price for both baskets compared to earlier individual years.

HHS reviewed a draft of this report and in its written comments noted that GAO's findings on stakeholder perspectives and changes in brand-name drug prices were consistent with its experience and CMS's drug price analysis. HHS stated that CMS will continue to monitor the Discount Program and Part D drug prices.

Contents

Figures

Abbreviations

CMS	Centers for Medicare & Medicaid Services
Discount Program	Medicare Coverage Gap Discount Program
Discount Program Agreement	Coverage Gap Discount Program Agreement
DR	delayed release
ER	extended release
FDA	Food and Drug Administration
HCERA	Health Care and Education Reconciliation Act of 2010
HCT	hydrochlorothiazide
HFA	hydrofluoroalkanes
HHS	Department of Health and Human Services
LA	long acting
LIS	low-income subsidy
MA-PDP	Medicare Advantage prescription drug plan
MedPAC	Medicare Payment Advisory Commission
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
NDC	national drug code
NDC-9	nine-digit national drug code
PBM	pharmacy benefit manager
PDE	prescription drug event
PDP	stand-alone prescription drug plan
PPACA	Patient Protection and Affordable Care Act
TPA	third-party administrator

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

September 28, 2012

The Honorable Max Baucus
Chairman
Committee on Finance
United States Senate

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Sander M. Levin
Ranking Member
Committee on Ways and Means
House of Representatives

The Honorable John D. Dingell
House of Representatives

In 2011, approximately 29 million Medicare beneficiaries were enrolled in Medicare's outpatient prescription drug benefit, known as Part D. Prior to 2011, many Medicare beneficiaries with Part D prescription drug coverage paid 100 percent of their drug costs while in the coverage gap or "donut hole." The coverage gap occurs between the initial and catastrophic coverage periods, during which Medicare payments reduce beneficiaries' costs. The Medicare Coverage Gap Discount Program (Discount Program), established by the Patient Protection and Affordable Care Act (PPACA) in 2010, was implemented in 2011 as part of an effort to assist beneficiaries who do not receive Part D's low-income subsidy (LIS) with their drug costs when they reach the coverage gap.[1]

[1]For purposes of this report, references to PPACA include the amendments made by the Health Care and Education Reconciliation Act of 2010 (HCERA). Pub. L. No. 111-148, § 3301,124 Stat. 119, 461 (2010), as amended by HCERA, Pub. L. No. 111-152, §§ 1101(b), (d), 124 Stat. 1029, 1037, 1039 (amending various sections of Subtitle D of Title XVIII of the Social Security Act (codified at 42 U.S.C. §§ 1395w-101 et seq.)). Beneficiaries receiving Part D's LIS have limited income and resources and are eligible for subsidies paid by Medicare to the drug plan in which they are enrolled. LIS beneficiaries are not eligible for the Discount Program.

Beginning in January 2011, PPACA required that drug manufacturers wishing to have their drugs covered under the Part D program participate in the Discount Program, which requires them to provide a 50 percent discount on the price that Part D plan sponsors[2] negotiate for brand-name drugs when beneficiaries reach the coverage gap.[3] Under PPACA, Medicare will provide a subsidy over time to cover more of beneficiaries' spending when they reach the coverage gap so that by 2020 the coverage gap is eliminated. The 50 percent discount that brand-name manufacturers must pay for brand-name drugs is permanent.

You raised concerns that manufacturers participating in the Discount Program may raise prices for brand-name drugs used by beneficiaries who are in the coverage gap more rapidly than for other drugs to offset the 50 percent discount that manufacturers are required to give these drugs. You also asked us to describe the oversight that the Centers for Medicare & Medicaid Services (CMS), located within the Department of Health and Human Services (HHS), provides of the new Discount Program and the potential effects of the new program. In this report, we describe (1) CMS's oversight activities for the Discount Program; (2) the perspectives of Medicare Part D plan sponsors, drug manufacturers, and pharmacy benefit managers (PBM) on the effects of the Discount Program; and (3) how prices changed before and after implementation of the Discount Program for brand-name drugs used by beneficiaries who did and beneficiaries who did not reach the coverage gap in 2011.

To describe CMS's oversight activities for the Discount Program, we reviewed relevant laws, such as PPACA, and regulations, as well as guidance that CMS provided to plan sponsors and drug manufacturers clarifying various policy and technical aspects of the Discount Program. We also reviewed CMS's Coverage Gap Discount Program Agreement (Discount Program Agreement), the contract between CMS and drug manufacturers outlining CMS's oversight responsibilities for the Discount Program and drug manufacturers' obligation to provide discounts for

[2]Plan sponsors, often private insurers, contract with the Centers for Medicare & Medicaid Services to offer the prescription drug benefit.

[3]A brand-name drug is a drug marketed under a proprietary, trademark-protected name. Pharmacy benefit managers may also negotiate brand-name drug prices on behalf of plan sponsors.

brand-name drugs to eligible beneficiaries in the coverage gap.[4] We also interviewed CMS officials to obtain information on CMS's oversight activities, including steps the agency has taken to monitor manufacturers' and plan sponsors' adherence to their Discount Program responsibilities, as outlined in the Discount Program Agreement, and whether the agency has reviewed outcomes related to the program.

We also interviewed a sample of Medicare Part D plan sponsors, PBMs, and drug manufacturers to describe their perspectives on the effects of the Discount Program. To select our sample of plan sponsors to interview, we used Medicare Part D enrollment data provided by CMS to identify the plan sponsors with the highest non-LIS beneficiary enrollment in Medicare Part D as of January 1, 2011.[5] We interviewed the seven largest plan sponsors that represented about 68 percent of total non-LIS enrollment in Medicare Part D as of January 1, 2011. Additionally, we interviewed three PBMs that contracted with at least one of the plan sponsors we interviewed. To select our sample of drug manufacturers to interview, we used 2011 Medicare Part D prescription drug event (PDE) data provided by CMS to identify the top 10 manufacturers whose brand-name drugs accounted for the highest total drug expenditures used by non-LIS Medicare Part D beneficiaries in the coverage gap in 2011.[6] Of the top 10 manufacturers, we interviewed 8 manufacturers that represented about 54 percent of the total expenditures for brand-name drugs used by non-LIS beneficiaries who reached the coverage gap in 2011. We used structured interview protocols to gather consistent information about the perspectives of each entity on the effects of the Discount Program, such as any changes in drug prices, rebate negotiations, and prescription drug benefits.[7]

[4]42 U.S.C. § 1395w-114a(b); 77 Fed. Reg. 22072, 22173 (Apr. 12, 2012) (to be codified at 42 C.F.R. § 2315). The Discount Program Agreement is signed between manufacturers and the Secretary of HHS.

[5]To identify the plan sponsors, we excluded plans with restricted enrollment, including employer-sponsored, Demonstration, and Programs of All-Inclusive Care for the Elderly.

[6]To identify the top 10 manufacturers, we excluded brand-name drug expenditures for beneficiaries enrolled in plans with restricted enrollment, including employer-sponsored, Demonstration, and Programs of All-Inclusive Care for the Elderly.

[7]Rebates are payments that manufacturers make to plan sponsors so that the sponsors encourage the use of certain drugs by their beneficiaries.

To describe how prices changed before and after implementation of the Discount Program for brand-name drugs used by beneficiaries who did and beneficiaries who did not reach the coverage gap in 2011, we analyzed the trend in Medicare Part D prices from January 2007 through December 2011 for two baskets of brand-name drugs used by non-LIS beneficiaries. The first basket of brand-name drugs included 77 high-expenditure brand-name drugs used by non-LIS beneficiaries while in the coverage gap in 2011 and the second basket included 78 high-expenditure brand-name drugs used by non-LIS beneficiaries who did not reach the coverage gap in 2011.[8] We compared price trends for these two baskets because brand-name drugs used by non-LIS beneficiaries while in the coverage gap in 2011 may be more susceptible to price increases, since manufacturers must provide a 50 percent discount for these drugs, compared with drugs used by non-LIS beneficiaries who did not reach the gap and thus were not subject to the discount.[9] For each of the drugs in the two baskets, we analyzed the median price, weighted by the utilization of each drug. The drug prices we analyzed were based on prices negotiated by plan sponsors and were affected by price changes made by manufacturers. We also conducted additional analyses of subsets of drugs of these baskets. For example, because a significant number of drugs overlapped both baskets (50 drugs), we compared price trends for the brand-name drugs that did not overlap. (See app. I for a detailed discussion of our methodology for examining brand-name drug price changes and app. II for a listing of the brand-name drugs in each basket.)

Our findings are limited to those sponsors, PBMs, and manufacturers we spoke with and are not representative of the effects observed across all of these types of entities. Additionally, any price changes we observed may not be directly related to the Discount Program since multiple factors can affect drug prices over time. We reviewed data we received from CMS for

[8]For the first basket, we selected high-expenditure drugs that were used while non-LIS beneficiaries were in the coverage gap and did not include high-expenditure drugs used by these beneficiaries during the deductible and initial coverage periods, which are prior to the gap, or those during the catastrophic coverage period, which is after the gap. Drugs can be high expenditure based on their price and utilization.

[9]While manufacturers did not know in advance specifically which individual beneficiaries would reach the coverage gap in 2011, there may have been an incentive to raise prices for brand-name drugs that were often used by beneficiaries who reached the coverage gap in prior years or by beneficiaries who were likely to have higher-than-average annual drug expenditures.

reasonableness and consistency, including screening for outliers. We also reviewed documentation and spoke with CMS officials about steps taken to ensure data reliability. Based on this review, we determined that the data used in this report were sufficiently reliable for our purposes. We conducted this performance audit from August 2011 through September 2012 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Medicare Part D Enrollment and Spending

Approximately 49 million elderly and disabled individuals were enrolled in Medicare in 2011, of which about 29 million were enrolled in Part D. Medicare beneficiaries obtain Part D coverage by choosing from multiple, competing plans offered by plan sponsors—often private insurers—that contract with CMS to offer the prescription drug benefit. About 63 percent of the approximately 29 million Part D beneficiaries were enrolled in stand-alone prescription drug plans (PDP), which add drug coverage to original fee-for-service Medicare and certain Medicare plans, and approximately 37 percent were enrolled in Medicare Advantage prescription drug plans (MA-PDP), which provide Medicare benefits and prescription drug coverage through a single privately managed plan (see table 1 for the number of beneficiaries enrolled by plan type).[10] Of the approximately 29 million beneficiaries enrolled in Medicare Part D, about 36 percent were LIS beneficiaries and approximately 64 percent were non-LIS beneficiaries (see table 1 for the number of beneficiaries enrolled in PDPs and MA-PDPs who were LIS and non-LIS).

[10]PDPs and MA-PDPs are offered by insurance companies and other private companies.

Table 1: Medicare Enrollment by Plan Type and Income Subsidy Status, 2011

Medicare enrollment	Number in millions
Total Medicare enrollment	**48.7**
Total Medicare Part D enrollment	**29.3**
Stand-alone prescription drug plans (PDP)	18.6
Medicare Advantage prescription drug plans (MA-PDP)	10.7
Total Medicare Part D enrollment	**29.3**
Non-low-income subsidy (LIS)	18.8
LIS	10.5

Source: Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds and Medicare Payment Advisory Commission (MedPAC).

Note: Total Medicare enrollment for 2011 is from the Board of Trustees Report and Medicare Part D enrollment figures are from MedPAC's analysis of April 2011 enrollment data. See Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2012 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (Washington, D.C.: Apr. 23, 2012) and Medicare Payment Advisory Commission, *March 2012 Report to the Congress: Medicare Payment Policy* (Washington, D.C.: Mar. 15, 2012).

In 2011, federal spending on Part D totaled approximately $67 billion, accounting for about 12 percent of total Medicare expenditures.[11] Medicare Part D spending depends on several factors, including the number of beneficiaries, their health status and extent of drug utilization, and the cost of drugs covered by Part D. In its 2012 report to Congress, the Medicare Payment Advisory Commission (MedPAC) reported that prices for individual Part D drugs (brand-name and generics) rose by an average of 18 percent cumulatively between January 2006 and December 2009.[12] To help keep Part D spending down, CMS relies on

[11]See Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2012 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* (Washington, D.C.: Apr. 23, 2012).

[12]MedPAC contracted with researchers at Acumen, LLC, to construct a series of volume-weighted price indexes for all drug and biologic prescriptions filled under Medicare Part D. The indexes do not reflect rebates from manufacturers, but do reflect discounts from pharmacies at the point-of-sale. MedPAC also reported that taking into account the substitution of generics for brand-name drugs, overall Part D prices rose 1 percent cumulatively between January 2006 and December 2009. Medicare Payment Advisory Commission, *March 2012 Report to the Congress: Medicare Payment Policy* (Washington, D.C.: Mar. 15, 2012). A generic drug is chemically equivalent to its branded counterpart and is generally marketed by multiple manufacturers under a nonproprietary name.

competing plan sponsors to negotiate drug prices for the beneficiaries in their plans.[13] Medicare Part D plan sponsors may contract with PBMs to negotiate price discounts with retail pharmacies and rebates with drug manufacturers for the drugs a plan covers, or plan sponsors may independently negotiate directly with pharmacies and manufacturers.[14] The price discounts that plan sponsors negotiate with pharmacies are based on drug prices that manufacturers establish and generally result in a lower price that a beneficiary pays at the point-of-sale. In comparison, the rebates that plan sponsors negotiate with drug manufacturers are passed on to plan sponsors who may use them to lower beneficiary costs including premiums.[15]

Medicare Part D Benefit and Plan Design

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which established Medicare Part D, required that all Part D plan sponsors offer a minimum set of benefits to beneficiaries, defined as the standard Part D benefit.[16] For non-LIS beneficiaries, this benefit features a deductible (a fixed dollar amount that beneficiaries must pay before coverage takes effect) and an initial coverage period during which the beneficiary pays a coinsurance (or percentage share of the drug's actual costs) for prescription drugs until the beneficiary reaches the initial coverage limit. After the initial coverage period, the beneficiary enters the coverage gap, which is followed by the catastrophic coverage period in which he or she pays a small amount of the total drug costs.[17]

[13]Federal law prohibits the Secretary of HHS from interfering with price negotiations between plan sponsors and drug manufacturers and pharmacies. 42 U.S.C. § 1395w-111(i).

[14]Plan sponsors may also contract with PBMs to help manage their prescription drug benefits, for example, by operating mail-order prescription services and administrative claims processing systems. A portion of the manufacturer's rebate may be retained by the PBM or the plan sponsor.

[15]A premium is a periodic payment that a beneficiary must make to be enrolled in a Part D plan and receive prescription drug coverage. Beginning in 2011, PPACA required beneficiaries with higher incomes to pay an income-related premium, meaning that they must pay higher premiums than beneficiaries with lower incomes. 42 U.S.C. § 1395w-113(a).

[16]Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071 (adding a new Part D to title XVIII of the Social Security Act) (codified at 42 U.S.C. §§ 1395w-101 et seq.).

[17]The standard parameters are adjusted each year based on the percentage increase in average per capita total Part D drug expenditures for beneficiaries.

Beneficiaries must also pay a monthly premium to be enrolled in a Part D plan. LIS beneficiaries do not pay the same out-of-pocket costs as non-LIS beneficiaries since they receive subsidies to assist them with their out-of-pocket drug costs.

In 2011, out-of-pocket costs for non-LIS beneficiaries in defined standard benefit plans in the initial coverage period included a $310 deductible and 25 percent coinsurance (with the plan paying the remaining 75 percent) until the total combined drug costs paid by the beneficiary and the Part D Plan reached the initial coverage limit of $2,840.[18] The beneficiary then entered the coverage gap until total drug costs reached the 2011 catastrophic coverage threshold of $6,447.50. Once this threshold was reached, the beneficiary paid the greater of either a $2.50 to $6.30 copayment or 5 percent coinsurance per prescription during the catastrophic period. Prior to 2011, non-LIS beneficiaries in the defined standard benefit plan were responsible for 100 percent of their drug costs while in the coverage gap.

MMA also allows plan sponsors to offer plans that are either actuarially equivalent to or exceed the defined standard benefit. These benefit plans can vary in design with regards to the monthly premiums, initial coverage limit, and cost-sharing arrangements such as copayments and coinsurance, but include the elements of the defined standard benefit. For example, plans with enhanced drug benefits may charge higher monthly premiums than defined standard benefit plans, but may offer a reduced or no deductible, charge a lower coinsurance amount than the 25 percent coinsurance during the initial coverage period, and provide some coverage for drugs when beneficiaries reach the coverage gap. Most Part D beneficiaries are enrolled in these actuarially equivalent or enhanced benefit plans.[19] Each plan also has a formulary (a list of the prescription drugs that it covers) and plan sponsors select the coinsurance or copay amount that beneficiaries must pay for each listed

[18]During the initial coverage period up until $2,840, the beneficiary paid a total of $942.50 in out-of-pocket costs ($310 for the deductible plus $632.50, which represents 25 percent coinsurance) while the plan paid $1897.50 (or 75 percent coinsurance).

[19]In 2011, over 90 percent of beneficiaries in PDPs and MA-PDPs were enrolled in actuarially equivalent or enhanced plans. Most of these beneficiaries, however, do not have coverage for brand-name drugs in the coverage gap. See Medicare Payment Advisory Commission, *March 2012 Report to the Congress: Medicare Payment Policy*.

drug.[20] Plan sponsors may require beneficiaries to pay a higher coinsurance or co-pay amount, for example, for certain high-cost drugs, such as specialty-tier eligible drugs that treat conditions such as cancer, multiple sclerosis, and rheumatoid arthritis.[21] Plan sponsors also select whether any utilization management practices apply for each listed drug, such as limits on the amount of drug that can be provided.[22]

Medicare Part D Coverage Gap Discount Program

The Discount Program began in January 2011 after being established in 2010 by PPACA to reduce beneficiaries' out-of-pocket drug costs when they reach the coverage gap. Non-LIS beneficiaries are eligible for the discount if they are enrolled in a PDP or MA-PDP, are not enrolled in a qualified retiree prescription drug plan, and have reached or exceeded the initial coverage limit during the year.[23] Beneficiaries that are enrolled in enhanced plans providing some coverage for brand-name drugs when they reach the coverage gap may also receive the discount after

[20]Sponsors must adhere to a minimum set of formulary requirements established in statute and regulation. Sponsors generally must include at least two drugs within each therapeutic category and class of covered Part D drugs. Exceptions are allowed, for example when there is only one drug in a particular category or class. In addition, CMS requires that formularies include "all or substantially all" drugs within six designated categories of clinical concern. *See* 42 U.S.C. § 1395w-104(b)(3)(C)(i); 42 C.F.R. § 423.120(b)(2)(2011); CMS, Medicare Prescription Drug Benefit Manual, Chapter 6, § 30.2.5 (2010).

[21]CMS allows plans to establish a specialty tier for high-cost drugs when their monthly cost exceeds a certain threshold, and in 2011 CMS established a threshold of $600. Standard benefit plans may not charge a coinsurance amount greater than 25 percent for such drugs. 42 C.F.R. § 423.578(a)(7)(2011); CMS, Medicare Prescription Drug Benefit Manual, Chapter 6, § 30.2.4 (2010).

[22]These utilization management practices can include (1) step therapy, which requires that a beneficiary try lower-cost drugs before a sponsor will cover a more costly drug; (2) prior authorization, which requires a beneficiary to obtain the sponsor's approval before a drug is covered for that individual; and (3) quantity limits, which restrict the dosage or number of units of a drug provided within a certain period of time. Utilization management practices are subject to CMS approval.

[23]To be eligible for the Discount Program, beneficiaries must not have not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold. Beneficiaries with such incurred costs would be eligible for catastrophic coverage. 42 U.S.C. § 1395w-114a(g)(1).

supplemental benefits are applied.[24] PPACA required that manufacturers wishing to have their brand-name drugs covered under the Medicare Part D program participate in the Discount Program. To participate in the Discount Program, manufacturers must sign an agreement with CMS to provide non-LIS beneficiaries a 50 percent discount on the plan-negotiated price for brand-name drugs at the point-of-sale when non-LIS beneficiaries reach the coverage gap.[25] In addition, PPACA stipulated that both the portion of drug costs for brand-name drugs paid by the beneficiary and the portion paid by the manufacturer count toward reaching the beneficiary's annual catastrophic coverage threshold.[26] As a result, beneficiaries' out-of-pocket costs will be significantly reduced. (See app. III for information about how the Discount Program works for beneficiaries at the point-of-sale for brand-name drugs.)

Separately, PPACA also included provisions that phase out the coverage gap gradually through 2020 by providing Medicare subsidies to help pay for the cost of brand and generic prescription drugs in the gap for non-LIS beneficiaries.[27] Specifically, beginning in 2013, Medicare will pay 2.5 percent of the plan-negotiated price for brand-name drugs.[28] Medicare will increase its subsidy to 25 percent for brand-name drugs by 2020, while manufacturers will continue to pay the 50 percent discount through 2020 and in subsequent years for a combined 75 percent payment towards brand-name drugs for beneficiaries. Additionally, beginning in January 2011, Medicare paid 7 percent of the plan-negotiated price for generic drugs while the beneficiary paid 93 percent of the cost when they

[24]For beneficiaries enrolled in enhanced benefit plans that have brand-name drug coverage while in the coverage gap, the 50 percent discount is applied to the amount the beneficiary owes, according to their supplemental coverage. 42 U.S.C. § 1395w-114a(c)(2). For example, a beneficiary with a $30 copayment for brand-name drugs while in the coverage gap pays $15 and the manufacturer pays $15, after applying the 50 percent discount to the copayment.

[25]42 U.S.C. § 1395w-114a(a). In 2011, over 99 percent of brand-name drug manufacturers participated in the Discount Program, according to CMS officials. The discount is only applicable for brand-name drugs and those covered under Part D. 42 U.S.C. § 1395w-114a(g)(2).

[26]42 U.S.C. § 1395w-102(b)(4)(E).

[27]PPACA, § 3301 (amending Part D of title XVIII) (codified at 42 U.S.C. §§ 1395w-101 et seq.).

[28]42 U.S.C. § 1395w-102(b)(2)(D).

reached the coverage gap.[29] Medicare will increase its subsidy to 75 percent for generic drugs by 2020.[30] CMS encourages beneficiaries to use generic drugs to reduce their out-of-pocket spending for drugs, which also helps keep Medicare Part D spending down. In 2010, about 75 percent of drugs dispensed in Medicare Part D were generic, according to CMS.[31] The coverage gap will be eliminated by 2020 as the beneficiary's coinsurance for brand-name and generic drugs will be reduced to 25 percent—the same coinsurance amount as required during the initial coverage period. See table 2 for beneficiary coinsurance and Medicare subsidy amounts for brand-name and generic drugs through 2020.

[29]42 U.S.C. § 1395w-102(b)(2)(C).

[30]For brand-name drugs, all applicable discounts paid by manufacturers count toward reaching the beneficiary's annual catastrophic coverage threshold limit. *See* 42 U.S.C. § 1395w-102(b)(4)(E). Since no such payments are made on behalf of beneficiaries in relation to generic drugs, only the amount the beneficiary pays for a generic drug counts toward reaching the threshold limit.

[31]The substitution of generic drugs for brand-name drugs has contributed to the slower-than-expected growth in Medicare Part D spending between 2006 and 2011. See Kaiser Family Foundation, *Medicare Part D Spending Trends: Understanding Key Drivers and the Role of Competition* (Washington, D.C.: May 2012).

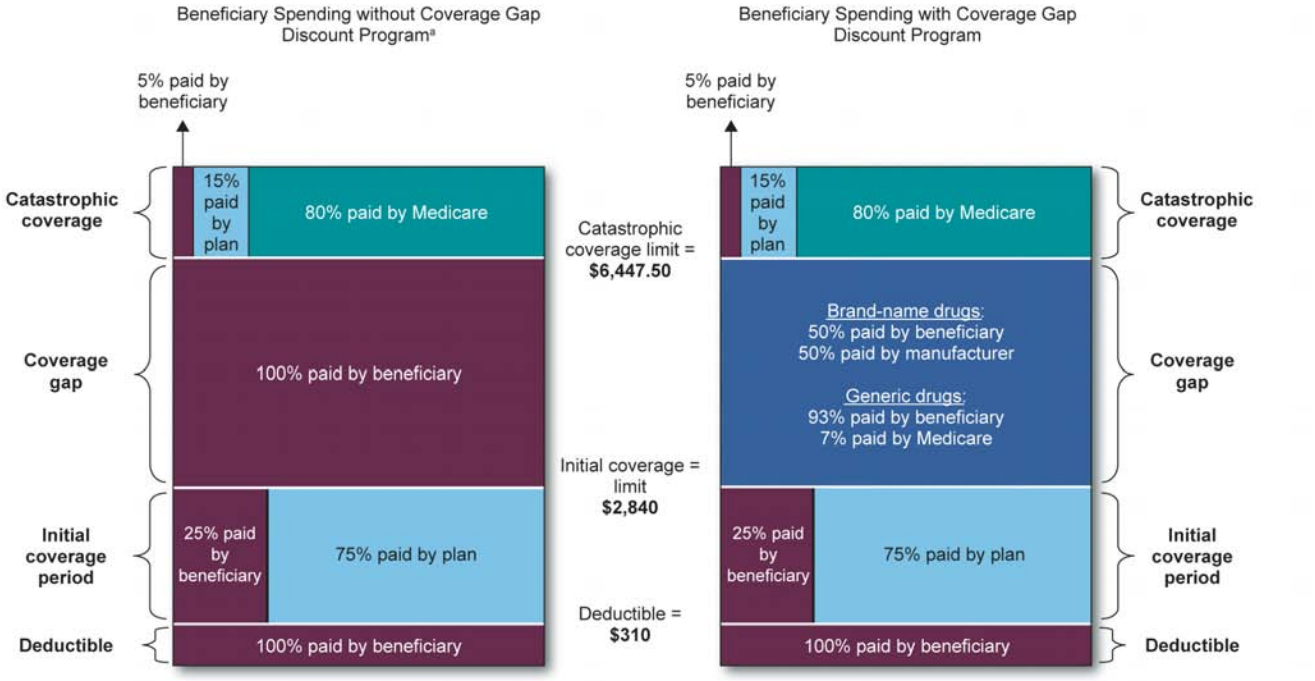
Table 2: Coinsurance Paid by Non-LIS beneficiaries While in the Coverage Gap for Brand-Name and Generic Drugs, 2011 to 2020

	Percent				
	Brand-name drugs			Generic drugs	
Calendar year	Beneficiary coinsurance	Medicare subsidy	Manufacturer discount	Beneficiary coinsurance	Medicare subsidy
2011	50%	0%	50%	93%	7%
2012	50	0	50	86	14
2013	47.5	2.5	50	79	21
2014	47.5	2.5	50	72	28
2015	45	5	50	65	35
2016	45	5	50	58	42
2017	40	10	50	51	49
2018	35	15	50	44	56
2019	30	20	50	37	63
2020	25	25	50	25	75

Source: CMS.

Figure 1 shows a comparison of a non-LIS beneficiary's out-of-pocket spending for prescription drugs when the beneficiary reaches the coverage gap under the standard benefit plan without and with implementation of the Discount Program in 2011. If the Discount Program was not in place, non-LIS beneficiaries in the standard benefit would have been responsible for $3,607.50 in drug costs during the coverage gap in 2011 ($6,447.50 annual catastrophic threshold - $2,840 initial coverage limit = $3,607.50). With the Discount Program, non-LIS beneficiaries would pay $1,803.75 in drug costs when using only brand-name drugs during the coverage gap.

Figure 1: Comparison of a Non-LIS Beneficiary's Out-of-Pocket Spending for Prescription Drugs in the Coverage Gap under the Standard Benefit in 2011, without and with the Medicare Coverage Gap Discount Program in Place



Source: GAO analysis of CMS information.

Note: Once the catastrophic threshold is reached, the beneficiary pays the greater of 5 percent coinsurance or copayments of $2.50 for generics or preferred multiple-source drugs and $6.30 for other drugs, including brand-name drugs. A multiple-source drug is one for which there is at least one other drug product rated as therapeutically and pharmaceutically equivalent. Therapeutically and pharmaceutically equivalent drugs have the same active ingredients and clinical effects. A preferred drug is a drug that is included on a plan's formulary for which beneficiary cost-sharing is lower (i.e., the drug has a preferred position), compared to a nonpreferred drug.

[a]This side of the figure is an example of what beneficiary out-of-pocket spending for prescription drugs would have been in 2011 if the Coverage Gap Discount Program had not been implemented.

Discount Program Responsibilities for Plan Sponsors, Drug Manufacturers, and CMS

Plan sponsors, drug manufacturers, and CMS each have responsibilities for carrying out the Discount Program. Plan sponsors are responsible for making payments at the point-of-sale for the 50 percent discount for brand-name drugs on behalf of manufacturers, providing information to pharmacies about beneficiaries and the drugs subject to the discount, and reporting discount amounts to CMS. In order for the discount to be provided at the point-of-sale to beneficiaries, plan sponsors determine: (1) that the drug is an applicable drug; (2) that the beneficiary is eligible for the discount; (3) that the pharmacy claim for the drug is wholly or partially in the coverage gap; and (4) the amount of the discount. After the

beneficiary receives the discount at the point-of-sale, plan sponsors are responsible for recording the amount of the discount that was paid for the drug, along with information such as the associated sales tax and dispensing fee.[32] The plan sponsors include this information on the PDE record, a summary record for each prescription that a beneficiary fills. Plan sponsors must submit PDE records to CMS.

Drug manufacturers are responsible for making payments to plan sponsors for the discounts sponsors provide on applicable drugs and maintaining up-to-date listings of drugs that are subject to the discount, as stated in the Discount Program Agreement. Manufacturers are required to reimburse plan sponsors for the discounts for applicable drugs that plan sponsors paid on their behalf at the point-of-sale. Manufacturers are also responsible for electronically listing and maintaining an up-to-date electronic Food and Drug Administration (FDA) registration and listing of all national drug codes (NDC) so that CMS and plan sponsors can accurately identify applicable drugs in the Discount Program.[33]

CMS is responsible for making prospective payments to plan sponsors, invoicing manufacturers, and overseeing the Discount Program, as stated in the Discount Program Agreement. CMS makes monthly Part D prospective payments to plan sponsors for providing prescription drug benefits to Medicare beneficiaries, which includes payments for providing discounts to beneficiaries. The prospective payments are calculated with information such as the number of beneficiaries enrolled in a plan and their projected drug costs. CMS is also responsible for aggregating and validating the discount amounts that plan sponsors have paid, as reported on the PDE records. Upon aggregating the amount of the discounts that plan sponsors have paid, CMS sends this information to its third-party administrator (TPA), which is responsible for invoicing the manufacturers on a quarterly basis. CMS also monitors plan sponsors', manufacturers', and the TPA's compliance with their program responsibilities.

[32]A dispensing fee is the amount paid to the pharmacy for dispensing a medication.

[33]An NDC is an identifying prescription drug product number that is registered and listed with the FDA. See http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm for the FDA's listing of NDCs (accessed July 3, 2012).

CMS Oversees Coverage Gap Discounts Provided by Plan Sponsors and Paid for by Manufacturers

CMS oversees the provision of discounts by plan sponsors to eligible beneficiaries who reach the coverage gap, and ensures that the discounts are paid for by drug manufacturers. CMS oversight activities include performing checks of prescription drug data to verify that plan sponsors provide accurate discounts at the point-of-sale to eligible beneficiaries who reach the coverage gap. CMS also tracks the payment of discounts by drug manufacturers to plan sponsors and has implemented a dispute resolution process to resolve manufacturer disputes about discounts. In addition, CMS performs other activities, such as monitoring beneficiary complaints, and has reported on certain Discount Program outcomes.

CMS Checks Prescription Drug Data to Verify That Plan Sponsors Provide Accurate Discounts to Eligible Beneficiaries

CMS performs 15 automated checks of PDE data specific to the Discount Program that verify whether plan sponsors have provided and accurately calculated discounts at the point-of-sale to eligible beneficiaries who reach the coverage gap.[34] The PDE data checks include verifying that plan sponsors have provided discounts to beneficiaries who are eligible for a discount; for example, by checking beneficiaries' LIS status and their accumulated drug costs to confirm that they have reached the coverage gap within the benefit year. The PDE data checks also verify whether plan sponsors have accurately calculated discounts for beneficiaries. For example, CMS calculates an expected discount amount based on the brand-name drug price that is recorded on the PDE, and compares it with the discount amount that the plan sponsor records on the PDE. CMS provides plan sponsors with detailed information about any errors the agency identifies through the PDE data checks. Plan sponsors are responsible for correcting these errors and resubmitting the PDE records to CMS.[35] CMS officials told us that an additional use of the PDE data checks is to prevent fraud in the Discount Program, since CMS uses PDE data to determine the final payment amounts owed to plan sponsors by comparing actual costs to the prospective payments that CMS makes to plan sponsors, which includes payment for the discounts plan sponsors provide to beneficiaries at the point-of-sale. CMS officials also told us they also review the validity of plan sponsors' PDE records for discounts as part of CMS's annual onsite audits of plan sponsors.

[34]CMS officials told us that the 15 PDE checks are included among the 150 PDE checks that CMS conducts for the Medicare Part D program.

[35]According to CMS, plan sponsors are able to resolve most errors and may contact CMS for assistance as needed.

CMS periodically provides guidance to plan sponsors about reporting Discount Program information on the PDE record and the agency's 15 PDE data checks. For example, in April 2010, CMS issued guidance to plan sponsors on the requirements and procedures for implementing the Discount Program, including how to calculate discounts for eligible beneficiaries enrolled in the defined standard benefit plan and how to record discount information using the PDE data fields that are specific to the Discount Program.[36] Since the Discount Program was implemented in January 2011, CMS has issued further guidance to plan sponsors regarding the 15 PDE data checks. For example, in September 2011, CMS issued a memo to plan sponsors that explained how CMS plans to conduct PDE data checks that verify the status of brand-name drugs that received discounts using the FDA's updated NDC directory, which identifies brand-name drugs.[37]

CMS Tracks Discount Payments by Manufacturers and Has a Process to Resolve Payment Disputes

CMS tracks the payment of discounts by drug manufacturers to plan sponsors and can impose penalties for failure to pay. CMS officials reported that they track manufacturers' payments to plan sponsors for discounts by reviewing confirmation reports that plan sponsors submit to the agency when they receive payments from manufacturers. Manufacturers receive quarterly invoices from the TPA of discount payments owed to plan sponsors based on aggregated PDE data.[38] Manufacturers pay plan sponsors directly and plan sponsors submit a confirmation report to CMS upon the receipt of these payments. To ensure manufacturers make payments to plan sponsors for discounts, CMS may impose civil monetary penalties on drug manufacturers that fail to pay plan sponsors for the discounts.[39] CMS officials told us a few

[36]CMS, *Prescription Drug Event (PDE) Record Changes Required to Close the Coverage Gap* (Baltimore, Md.: Apr. 30, 2010).

[37]CMS, *Update on Part D National Drug Code Edits* (Baltimore, Md.: Sept.12, 2011).

[38]Three of the eight manufacturers we interviewed told us that they experienced problems with handling the quarterly invoices because the data files were provided in an outdated format, which required additional resources to program and interpret the invoice data. The TPA has other responsibilities related to the invoicing of manufacturers, including notifying manufacturers of invoice errors and making adjustments as needed to quarterly invoices. CMS officials told us they frequently monitor the TPA's performance via phone, e-mail, and meetings. CMS also plans to conduct its first audit and onsite visit of the TPA in 2012.

[39]CMS requires manufacturers to pay all applicable discounts to plan sponsors within 38 days of receipt of the quarterly invoices.

manufacturers have been late in submitting payments to plan sponsors due to technical issues, and that one manufacturer did not submit payment because the company went bankrupt.[40] CMS officials said they have not imposed any penalties on manufacturers as of July 2012.

CMS has implemented a dispute resolution process that allows manufacturers to dispute discounts they have paid to plan sponsors if they find problems with the quarterly invoices. Manufacturers can submit a dispute within 60 days of receipt of the quarterly invoices to the TPA, which is responsible for determining if the dispute is valid and makes adjustments to manufacturers' invoices as necessary. Manufacturers have the right to appeal the TPA's determination through an independent review entity established by CMS.[41] If the manufacturer disagrees with the independent review entity's determination, it may request the review of CMS, with CMS having the final decision on the dispute determination. In March 2012, CMS issued guidance providing manufacturers with detailed information about the basis for submitting disputes and CMS's process for evaluating dispute submissions.[42] For example, CMS explained that manufacturers may submit a dispute for a discount amount included in an invoice because they believe it is too high, and such disputes would be evaluated by analyzing the drug's price relative to all other PDE records for the same drug. If it is determined that the price falls within an acceptable range, the dispute would be denied.

[40]CMS officials told us the agency has not determined what entity would be financially liable for making quarterly invoice payments if the company that went bankrupt does not pay these invoices.

[41]In October 2011, CMS issued updated guidance on the dispute resolution process that expanded the time frames for manufacturers to appeal the TPA's determinations to the independent review entity from 60 days to 90 days. See CMS, *Medicare Coverage Gap Discount Program – Updated Guidance* (Baltimore, Md.: Oct. 28, 2011).

[42]CMS, *Medicare Coverage Gap Discount Program – Dispute Resolution* (Baltimore, Md.: Mar. 5, 2012). Prior to CMS's issuance of the March 2012 guidance, three of the eight manufacturers we interviewed told us that they wanted more guidance from CMS regarding the dispute resolution process, including more information on how to submit disputes of discount payments to the TPA.

CMS Performs Other Oversight Activities and Reports on Certain Discount Program Outcomes

CMS performs other oversight activities of the Discount Program that include maintaining codes, identifying drugs covered under the program, monitoring beneficiary complaints, and conducting audits of manufacturers:

- The agency maintains a list of codes (called labeler codes) identifying drugs covered under the Discount Program, which it makes publicly available on the CMS website.[43] CMS checks that manufacturers that participate in the Discount Program are providing discounts on brand-name drugs associated with this list of labeler codes.

- CMS officials told us they monitor and resolve beneficiary complaints—expressions of dissatisfaction about the Medicare program, including concerns about providers and health plans—related to the Discount Program through their Part D Complaints Tracking Module. Beneficiaries submit the complaints, for example, by calling the 1-800-MEDICARE toll-free number or submitting an online Medicare complaint form. CMS officials said that, as of June 30, 2012, they have received and resolved 147 beneficiary complaints about the Discount Program, including complaints from beneficiaries who reported they reached the coverage gap and did not receive discounts, who received incorrect discounts, or who had concerns about how the discount was calculated.

- CMS may periodically audit drug manufacturers regarding information about the Discount Program that they are required to submit to the agency, including NDC expiration dates and labeler codes. Manufacturers rely on this information when they submit disputes of discounts from the quarterly invoices. CMS officials told us they have not conducted any of these audits as of July 2012.

CMS also ensures that information that may identify beneficiaries is not disclosed in any capacity under the Discount Program, as stated in the Discount Program Agreement. In order to protect beneficiary information, CMS initially decided not to invoice manufacturers for low-volume claims—claims for a specific drug submitted by 10 or fewer beneficiaries at the same pharmacy—because they were concerned that certain

[43]Labeler codes are the first five digits of the NDC and identify the company that manufacturers a drug. Manufacturers submit this information to CMS to indicate what drugs are covered under the Discount Program.

information from these claims, such as the identity of the pharmacy, may be used to identify beneficiaries.[44] After further evaluation of the policy, CMS issued guidance in January 2012 stating that the agency would invoice manufacturers for low-volume claims; CMS officials told us they had determined that beneficiary information could not be identified from such invoices.[45]

In addition, CMS has stated that the agency conducts other monitoring activities of the Discount Program, which include reporting on certain outcomes of the program and monitoring Medicare Part D drug prices. For example, CMS reported that over 3.7 million beneficiaries who reached the coverage gap received discounts, with an average of $613 in discounts per beneficiary in 2011.[46] CMS officials told us they also monitor Medicare Part D brand-name drug prices annually.[47] CMS will continue its process of monitoring drug prices, using data from 2011, which will take into account any effects on prices from the Discount Program and other factors.[48] CMS officials further explained that because many factors, including time, can affect changes in drug prices, the agency may not be able to separate out such effects on prices from the time the Discount Program was introduced.

[44]Five of the eight manufacturers we interviewed reported that their financial reporting was impacted by not being invoiced for low-volume claims. Three of the seven plan sponsors we interviewed also expressed concerns about not receiving payment from manufacturers for low-volume claims.

[45]See CMS, *Medicare Coverage Gap Discount Program – Update on Low-Volume Claims* (Baltimore, Md.: Jan. 27, 2012). CMS officials told us that manufacturers have been invoiced for all outstanding low-volume claims as of March 2012.

[46]See CMS website, "Plan Payment, Coverage Gap Discount Program, Coverage Gap Discount Data Spreadsheets," https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/CGDP.html (accessed Aug. 1, 2012).

[47]For example, CMS has analyzed changes in drug prices that are reported by plan sponsors on the Medicare Prescription Drug Plan Finder, an online tool that allows beneficiaries to compare plan and drug cost information for Medicare Part D plans.

[48]CMS officials stated that they plan to conduct this analysis after CMS reconciles the differences between its prospective payments and actual expenditures for 2011.

Plan Sponsors, PBMs, and Manufacturers Had Different Perspectives on Aspects of the Drug Pricing and Plan Design Effects of the Discount Program

Plan sponsors, PBMs, and drug manufacturers we spoke with had different perspectives on aspects of the drug pricing and plan design effects of the Discount Program, which include drug prices, rebates, formularies, plan benefit design, and utilization management practices. Most plan sponsors and PBMs told us they believe the Discount Program may have been a factor in the rising prices of some brand-name drugs, while most manufacturers told us the Discount Program has not affected the prices of brand-name drugs they negotiate with sponsors and PBMs. The three PBMs we interviewed also told us they observed that some manufacturers decreased the amount of rebates for the brand-name drugs they offered, which they believe occurred as a result of the Discount Program. In comparison, most of the plan sponsors did not observe manufacturers decrease rebate amounts and most manufacturers reported no effects on their rebate negotiations as a result of the Discount Program. Most plan sponsors and PBMs also reported that the Discount Program did not affect their Part D plan formularies, plan benefit design, or utilization management practices.

Most Plan Sponsors and PBMs Believe the Discount Program May Have Been a Factor in Rising Drug Prices, While Most Manufacturers Said It Has Not

Six of the seven plan sponsors and two of the three PBMs we interviewed told us they believe the Discount Program may have been a contributing factor in the rising prices of brand-name drugs by some manufacturers.[49] Some sponsors and one PBM told us they believe that some manufacturers raised prices for their brand-name drugs to recoup the costs of the discounts that they anticipated paying. Some of these sponsors and one PBM based their observations on reviews of drug pricing data; for example, one plan sponsor told us it reviewed PDE data. Two of these plan sponsors and one PBM also told us they observed such price increases occurring as early as 2010—when the Discount Program was announced—and continuing through 2012. For example, one plan sponsor and one PBM told us that they attributed the Discount Program as a factor in rising brand-name drug prices they observed from 2010 to 2011 based on analyses of their own drug pricing data.

[49]The remaining plan sponsor we interviewed told us it did not observe changes to brand-name drug prices that it believes occurred as a result of the Discount Program. The remaining PBM told us while it has observed rising brand-name drug prices, the PBM cannot attribute the Discount Program as a factor.

Six of the eight manufacturers we interviewed, in comparison, believe that the prices of their brand-name drugs negotiated with plan sponsors and PBMs have not been affected by the Discount Program. One of the two remaining manufacturers said that it considered the Discount Program as a factor when negotiating drug prices, but other factors, such as whether a given drug has competitors in the market, had more influence over negotiations. The other remaining manufacturer told us it was still evaluating the impact of the Discount Program and therefore could not determine whether it will affect or has affected brand-name drug prices.

PBMs, Plan Sponsors, and Manufacturers Had Different Observations on the Effects on Rebates as a Result of the Discount Program

The three PBMs we interviewed told us they observed that some drug manufacturers decreased the amount of rebates they offered for brand-name drugs, which they believe occurred as a result of the Discount Program.[50] One PBM observed that this was occurring among some manufacturers of specialty-tier-eligible drugs. Another PBM also told us it observed these effects beginning as early as 2010, prior to the implementation of the Discount Program in 2011.

Four of the seven plan sponsors we interviewed told us they did not observe decreased rebates as a result of the Discount Program. Three of these four plan sponsors told us that, while they did not observe decreased rebates, they believe manufacturers may likely decrease the amount of rebates they offer in the future and, according to two plan sponsors, they expect the decreases to be a result of manufacturers trying to recoup the costs of the discounts manufacturers are paying for some drugs. The remaining one of these four plan sponsors told us it has not observed any changes to rebate amounts because it has worked with manufacturers to maintain the same rebate levels offered prior to the Discount Program. In comparison, two plan sponsors told us they did observe some manufacturers decrease the amount of rebates they offer, and one of these plan sponsors told us it believes this occurred as a result of the Discount Program. The remaining seventh plan sponsor we spoke with did not specifically address the Discount Program's effect on decreased rebate amounts.

[50]The PBMs were speaking about the rebates they typically negotiate on behalf of the plan sponsors they represent. Manufacturers provide rebate payments to plan sponsors to encourage the use of certain drugs, and rebates result in overall lower Medicare spending for prescription drugs.

Six of the eight manufacturers we interviewed told us that the Discount Program did not change their rebate negotiations with plan sponsors and PBMs. However, two manufacturers told us that the Discount Program has changed some aspects of their rebate negotiations. For example, one of these two manufacturers told us it has established limits with plan sponsors regarding the rebate amounts it will pay to plan sponsors as a result of the discounts it has to pay for some drugs. The other manufacturer also told us that it has taken the Discount Program's effect into account when entering into rebate negotiations because paying for the discounts affects its profitability.

Most Plan Sponsors and PBMs Reported That the Discount Program Did Not Affect Formularies, Plan Benefit Design, or Utilization Management Practices

Most plan sponsors and PBMs we interviewed reported that the Discount Program has not affected their Medicare Part D plan formularies, plan benefit designs, and drug utilization management practices.[51] All seven plan sponsors and two of the three PBMs we interviewed told us that Part D plan formularies have not changed as a result of the Discount Program. In addition, most of these plan sponsors and PBMs told us that the placement of brand-name drugs on plan formularies, including specialty-tier eligible drugs, was not affected by the Discount Program.[52] In comparison, one PBM told us that formulary placement changes have occurred more frequently as a result of some manufacturers decreasing the amount of rebates they offer for brand-name drugs. In particular, this PBM has observed fewer brand-name drugs included on plan formularies as well as fewer brand-name drugs placed on formularies in preferred positions, which result in lower beneficiary cost-sharing for those drugs.[53] In addition to plan formularies, the seven plan sponsors we spoke with told us that the Discount Program has not affected the plan benefit design or drug utilization management practices of their Part D plans. For example, one of these plan sponsors told us that the Discount Program

[51]The PBMs were speaking about the formularies of the plan sponsors for which they conduct rebate negotiations.

[52]Two of these plan sponsors said they removed some brand-name drugs from formularies because the manufacturers who produced the drugs did not participate in the Discount Program.

[53]In order to encourage the use of certain drugs among beneficiaries, manufacturers may pay a formulary rebate to a plan for placing a certain drug in a preferred position on the plan's formulary. In exchange for the rebate, the plan may charge a lower copayment to the beneficiary for the drug in the preferred position, compared to nonpreferred brand-name drugs, resulting in a lower cost for the beneficiary.

has not been a factor in any plan benefit design changes and that it bases its plan benefit design on factors such as the ability to compete for Medicare Part D beneficiaries.

Prices Increased at a Similar Rate for Brand-Name Drugs Used by Beneficiaries in the Coverage Gap and by Those Who Did Not Reach the Gap

We found that prices for brand-name drugs used by beneficiaries in the coverage gap increased similarly to those used by beneficiaries who did not reach the gap, before and after the Discount Program was implemented in January 2011.[54] From January 2007 to December 2010, prior to the implementation of the Discount Program, the median price (weighted by the utilization of each drug) for the basket of 77 brand-name drugs used by beneficiaries in the coverage gap increased 36.2 percent (see fig. 2).[55] When measured across the same period, the median price for the basket of 78 brand-name drugs used by beneficiaries who did not reach the coverage gap also increased at a similar rate of 35.2 percent.[56] During the first year with the Discount Program (from December 2010 through December 2011), the median prices for the two baskets increased equally at a rate of about 13 percent.[57]

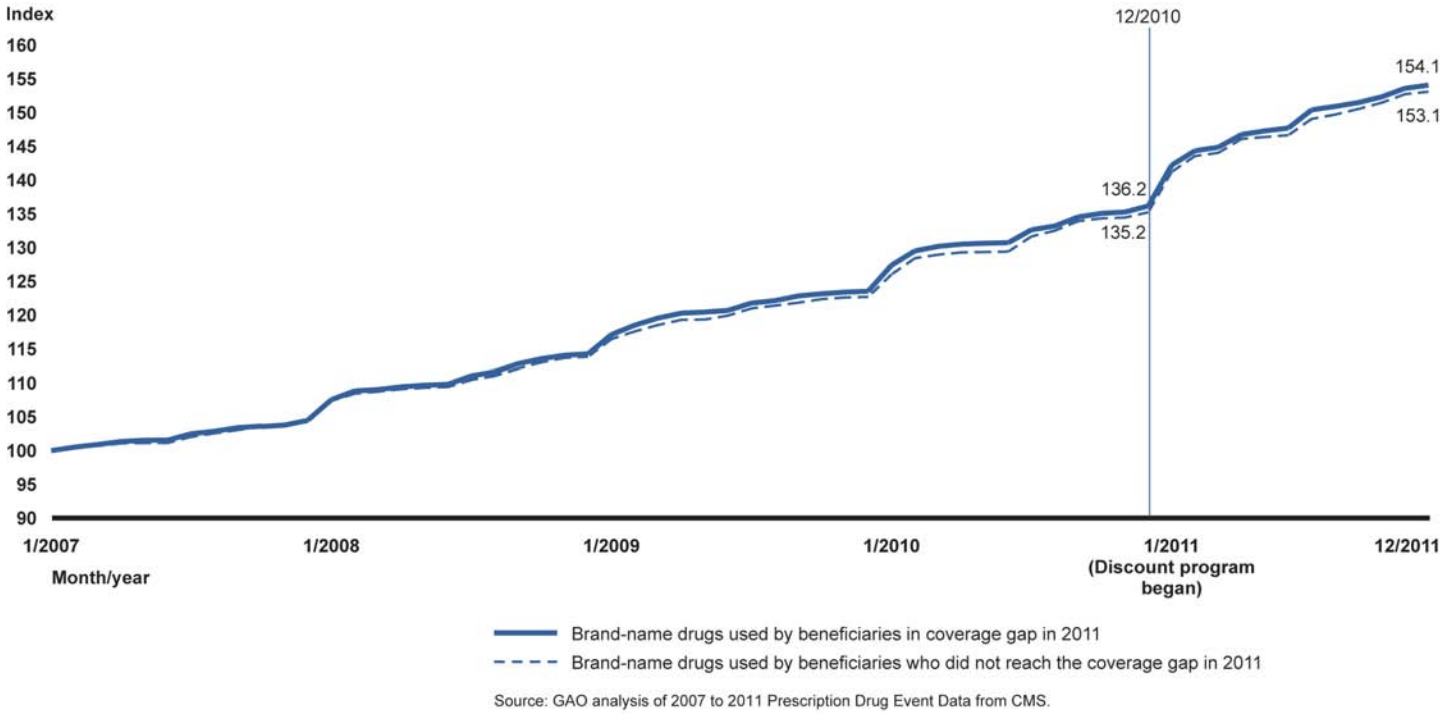
[54]We examined whether high-expenditure brand-name drugs used by beneficiaries in the coverage gap may be more susceptible to price increases by drug manufacturers than those used by beneficiaries who did not reach the gap.

[55]The point-of-sale price we analyzed is affected by price changes made by the manufacturer and reflects discounts that Part D plans have negotiated with pharmacies but does not include certain price concessions such as drug manufacturer rebates. While manufacturer rebates lower overall spending for drugs, manufacturer rebates are generally not passed onto the beneficiary at the point-of-sale.

[56]The baskets of brand-name drugs represent those used by beneficiaries in the coverage gap in 2011 and those used by beneficiaries who did not reach the coverage gap in 2011.

[57]The basket of drugs used by beneficiaries in the coverage gap included eight specialty-tier-eligible drugs, which are high-cost drugs, while the basket of drugs used by beneficiaries who did not reach the coverage gap did not include specialty-tier-eligible drugs. During the first year with the Discount Program (from December 2010 through December 2011), the median price for the specialty-tier-eligible drugs increased at a slower rate (8.8 percent) than the non-specialty-tier-eligible drugs (13.4 percent) in the basket of drugs used by beneficiaries in the coverage gap.

Figure 2: Price Indexes for Brand-Name Drugs Used by Medicare Part D Beneficiaries in the Coverage Gap and by Those Who Did Not Reach the Gap in 2011



Source: GAO analysis of 2007 to 2011 Prescription Drug Event Data from CMS.

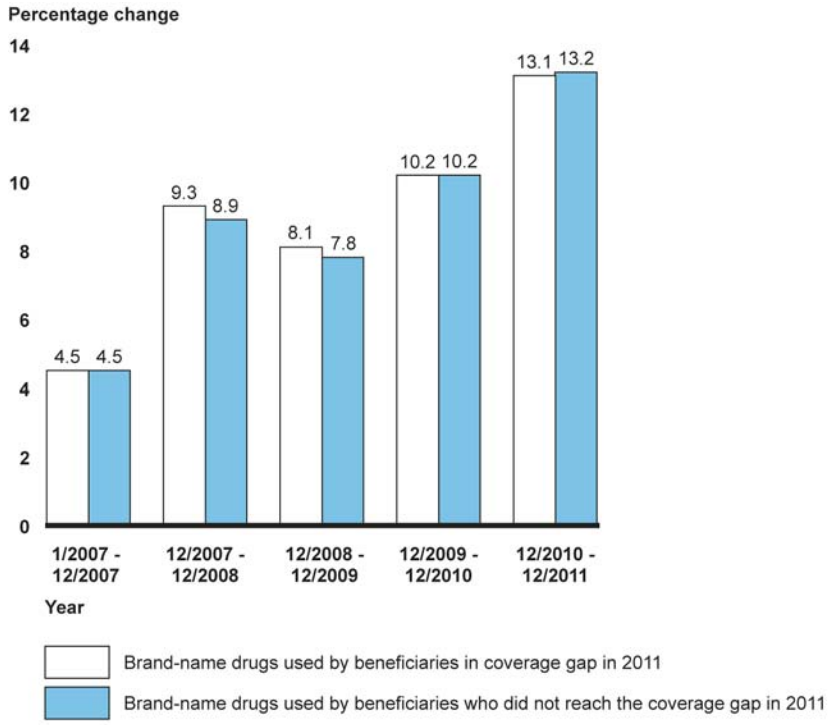
Note: The price indexes are for two baskets of high-expenditure brand-name drugs that were used by Medicare Part D beneficiaries who did not receive a low-income subsidy (LIS). Drugs can be high expenditure based on their price and utilization. The index values of 136.2 and 154.1 indicate increases of 36.2 and 54.1 percent in the median prices for the basket of brand-name drugs used by Medicare Part D beneficiaries in the coverage gap in 2011, from January 2007 to December 2010 and from January 2007 to December 2011. The index values of 135.2 and 153.1 indicate increases of 35.2 and 53.1 percent in the median price for the basket of brand-name drugs used by beneficiaries who did not reach the coverage gap in 2011, from January 2007 to December 2010 and from January 2007 to December 2011.

The median prices for the two baskets of brand-name drugs also increased similarly on an annual basis, from 2007 to 2011, with the greatest increase in price for both baskets occurring the first year with the Discount Program from December 2010 through December 2011 (see fig. 3).[58] For example, from December 2009 through December 2010 the

[58]The change in median price for 2007 is calculated from January 2007 through December 2007. In later years, the annual change in median price is calculated from December through December.

median price for the basket of drugs used by beneficiaries in the coverage gap and for the basket of drugs used by beneficiaries who did not reach the coverage gap each increased 10.2 percent. The greatest annual percent increase for the two baskets of brand-name drugs occurred from December 2010 through December 2011, during which time the median price increased 13.1 percent for the basket of brand-name drugs used by beneficiaries in the coverage gap and 13.2 percent for the basket of brand-name drugs used by beneficiaries who did not reach the coverage gap. In addition, the average annual rate of increase for the basket of brand-name drugs used by beneficiaries in the coverage gap was 9.2 percent over the entire period (January 2007 to December 2011), compared with a 9.0 percent increase for the other basket of drugs.

Figure 3: Annual Percent Change in Price for Brand-Name Drugs Used by Medicare Part D Beneficiaries in the Coverage Gap and by Those Who Did Not Reach the Gap in 2011



Source: GAO analysis of 2007 to 2011 Prescription Drug Event Data from CMS.

Note: The percentage changes are for two baskets of high-expenditure brand-name drugs that were used by Medicare Part D beneficiaries who did not receive a low-income subsidy (LIS). Drugs can be high expenditure based on their price and utilization. The change in median price from January 2007 through December 2007 is expressed as an annual percentage change.

We continued to find similar price increases for each basket of unique brand-name drugs during the first year with the Discount Program after removing the 50 drugs that overlapped both baskets. During the first year of the Discount Program, the median prices for the two baskets of unique drugs increased by over 12 percent: 12.3 percent for the 27 unique drugs used by beneficiaries in the coverage gap and 12.9 percent for the 28 unique drugs used by beneficiaries who did not reach the coverage gap.

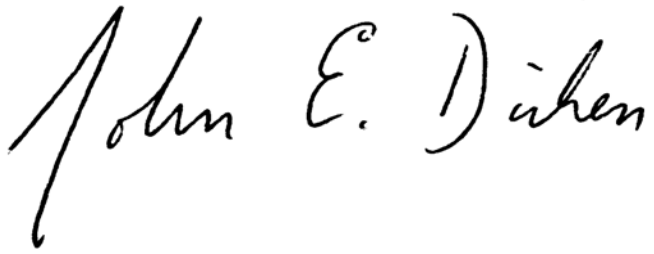
While many factors affect drug prices, such as the availability of competing drugs to treat the same condition and manufacturing and marketing costs, increasing brand-name drug prices can increase out-of-pocket spending for some beneficiaries in the coverage gap as well as increase overall Part D spending. Thus, continued monitoring of brand-name drug prices and manufacturer rebates will be important as the Discount Program matures.

Agency Comments

HHS reviewed a draft of this report and in its written comments noted that our finding on the perspectives of stakeholders (Medicare Part D plan sponsors, drug manufacturers, and PBMs) on the effects of the Discount Program is consistent with HHS's expectations and experience. HHS commented that our finding on price changes before and after implementation of the Discount Program for brand-name drugs used by Medicare Part D beneficiaries who did and did not reach the coverage gap is also consistent with HHS's expectations and experience. HHS further noted that our finding on brand-name drug price changes is similar to the results of CMS's own analysis of drug price data, which used a different methodology. HHS commented that CMS will continue to monitor the Discount Program to ensure that discounts on brand-name drugs are applied accurately and in a timely manner for Medicare Part D beneficiaries. In addition, HHS noted that CMS will continue to monitor Part D drug prices as well as the impact of drug prices on the Medicare Part D program. HHS's comments are printed in appendix IV.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services and interested congressional committees. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have questions about this report, 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 report. GAO staff members who made key contributions to this report are listed in appendix V.



John E. Dicken
Director, Health Care

Appendix I: Methodology for Examining Brand-Name Drug Price Trends

To describe how prices changed before and after implementation of the Medicare Coverage Gap Discount Program (Discount Program) for brand-name drugs, we compared the trend of Medicare Part D prices from January 2007 to December 2011 for a basket of brand-name drugs used by beneficiaries in the coverage gap with a basket of brand-name drugs used by beneficiaries who did not reach the gap in 2011. We compared price trends for these two baskets because brand-name drugs used by beneficiaries in the coverage gap in 2011—the year the Discount Program began—may be more susceptible to price increases, since manufacturers must provide a 50 percent discount for these drugs compared with drugs used by beneficiaries that do not reach the gap and thus are not subject to the discount.[1] We limited our analyses of Medicare Part D prices to those brand-name drugs that had high expenditures—based on price and utilization—used by beneficiaries who did not receive a low-income subsidy (LIS) and who were enrolled in stand-alone prescription drug plans (PDP) and Medicare Advantage prescription drug plans (MA-PDP).[2]

We created two fixed baskets of high-expenditure brand-name drugs using prescription drug event (PDE) data obtained from the Centers for Medicare & Medicaid Services (CMS) to analyze the trend of Medicare Part D prices. We began by selecting: (1) the top 100 brand-name drugs, based on total expenditures, used by non-LIS beneficiaries in PDPs and MA-PDPs in the coverage gap in 2011 and (2) the top 100 brand-name drugs, based on total expenditures, used by non-LIS beneficiaries in

[1]While manufacturers did not know in advance specifically which individual beneficiaries would reach the coverage gap in 2011, there may have been an incentive to raise prices for brand-name drugs that were often used by beneficiaries who reached the coverage gap in prior years or by beneficiaries who were likely to have higher-than-average annual drug expenditures.

[2]We excluded LIS beneficiaries because they are not eligible for the Discount Program. To focus on plans available to eligible beneficiaries, we excluded plans with restricted enrollment, including employer-sponsored, Demonstration, and Programs of All-Inclusive Care for the Elderly. We used CMS's monthly enrollment plan files, which are publicly available, to identify plans with restricted enrollment.

PDPs and MA-PDPs who did not reach the coverage gap in 2011.[3] We identified the top 100 brand-name drugs for each basket by using the nine-digit national drug code (NDC-9).[4] We determined the brand-name status of each NDC-9 by using FDA's NDC directory, which CMS uses to identify whether a drug is a brand-name drug and therefore eligible for a 50 percent discount under the Discount Program.[5] We determined total expenditures for each NDC-9 by aggregating the amount paid at the point-of-sale for all PDE records corresponding to a given NDC-9.[6] The amount paid at the point-of-sale included the ingredient cost (the drug's price negotiated by the beneficiary's Part D plan), sales tax, dispensing fee, and vaccination fee, if applicable.[7] After identifying the top 100 high-expenditure brand-name drugs by NDC-9 in each basket, we excluded those NDC-9s that did not have at least 25 PDE records in each month of

[3]The 2011 PDE data included PDE records submitted to CMS through February 16, 2012, and did not include all PDE records for 2011 because CMS may accept PDE records for up to 24 months following the end of the calendar year. CMS officials told us that in the past they have observed that about 10 to 15 percent of the PDE records were submitted after the calendar year. CMS officials further noted that these additional PDE records are often for adjustments for previously submitted claims rather than for new claims. We included PDE records for claims in the coverage gap period that straddled other periods, such as the catastrophic coverage period, because the 50 percent discount applies to the portion of the drug price that falls in the coverage gap.

[4]NDCs are the universal product identifiers for drugs for human use. The Food and Drug Administration (FDA) assigns the first segment of the NDC, which identifies the firm that manufactures, repackages, or distributes a drug; the second segment identifies a specific strength, dosage form, and formulation for a particular drug; and the third segment identifies package size. Three-segment NDCs are denoted by 11 digits while two-segment NDCs are denoted by 9 digits, and do not account for package size. Because our analysis focused on NDCs with the same drug name and strength, we based our analysis on NDC-9s instead of NDC-11s.

[5]To identify characteristics of brand-name drugs in each basket (e.g., drug name, strength), we used the July 2011 Red Book, published by Thomson Reuters.

[6]Per CMS guidance for the Discount Program, we excluded PDE records for drugs not covered under Medicare Part D or that were compound drugs (drugs that are prepared by a pharmacist who mixes or adjusts drug ingredients to customize a medication). We also excluded PDE records in which the price the beneficiary paid for a drug may have been different than the drug price the beneficiary's plan negotiated (e.g., because the beneficiary filled the prescription at a pharmacy not in the plan's network) or the drug was not included in the beneficiary's plan formulary.

[7]When plan sponsors or pharmacy benefit managers on behalf of plan sponsors negotiate drug prices with pharmacies, they typically negotiate discounts off a price that is established by manufacturers. A vaccination fee is the amount paid to a pharmacy or physician to cover the cost of administering a vaccination.

our analysis, from January 2007 to December 2011, for data reliability purposes. After completing these data steps, we had two fixed baskets of drugs for which we could follow monthly prices throughout the period of our analysis. The fixed baskets included 77 brand-name drugs used by non-LIS beneficiaries in the coverage gap in 2011 and 78 brand-name drugs used by non-LIS beneficiaries who did not reach the coverage gap in 2011 (see app. II for a list of the brand-name drugs included in each basket).[8]

To analyze Medicare Part D price trends for the two baskets of brand-name drugs, we created utilization-weighted price indexes using PDE data to track the monthly change in the median ingredient cost per unit for all drugs in each basket from January 2007 to December 2011.[9] We used the median because it is not sensitive to the presence of extreme measurement errors. The ingredient cost reflects discounts negotiated with pharmacies but not certain price concessions such as drug manufacturer rebates.[10] We tracked the ingredient cost for our analysis because it is subject to the 50 percent discount by manufacturers for brand-name drugs under the Discount Program and is affected by price changes made by the manufacturer. We tracked the ingredient cost per unit to account for varying quantities dispensed for a drug at the point-of-sale. We performed several data edits involving the quantity dispensed and ingredient cost per unit variables to further improve data reliability.[11]

[8]For the first basket, we selected high-expenditure drugs that were used while non-LIS beneficiaries were in the coverage gap and did not include high-expenditure drugs used by these beneficiaries during the deductible and initial coverage periods, which are prior to the gap, or those used during the catastrophic coverage period, which is after the gap.

[9]Specifically, we used the Fisher price index, a commonly used price index formula, to measure the change in price per unit for each basket. The Fisher price index minimizes the problem of understating or overstating price changes by using the utilization from the first and last period of our analysis as weights. We used drug utilization from the first and last month of our analysis as weights. We calculated the ingredient cost per unit by dividing the drug's ingredient cost by the quantity dispensed. The quantity dispensed is the total number of units, grams, or milliliters, and corresponds to the relevant unit of measurement for a drug.

[10]In 2011, CMS began collecting rebate information at the NDC level for the prior year (2010). CMS accounts for price concessions, such as rebates, at an aggregate level as part of its process to reconcile prospective payments with actual drug expenditures for each Part D plan sponsor.

[11]For example, we made adjustments to the quantity dispensed variable when reported values were less than 1 or greater than 1,000 (i.e., indicating the quantity may have been reported in incorrect units).

We then trimmed the data to remove outliers.[12] To weight the baskets, we multiplied the monthly median ingredient cost per unit by each drug's relative utilization, calculated as the ratio of the drug's quantity dispensed to the total quantity dispensed for all drugs in the basket. To create the monthly price indexes for each basket, we summed the resulting weighted median ingredient cost per unit of all the drugs in the basket and divided the resulting value by the entire basket's weighted median ingredient cost per unit as of January 2007. Each price index began with a value 100 as of January 2007.

To further analyze Medicare Part D price trends, we calculated monthly changes in the median ingredient cost per unit of subsets of drugs of the two baskets of drugs. First, because a significant number of drugs—50—overlapped both baskets, we compared price trends for the brand-name drugs that did not overlap.[13] Twenty-seven brand-name drugs were included only in the basket of drugs used by non-LIS beneficiaries in the coverage gap in 2011 and 28 were included only in the basket of drugs used by non-LIS beneficiaries who did not reach the coverage gap in 2011. Second, within the basket of drugs used by beneficiaries in the coverage gap in 2011, we compared specialty-tier-eligible drugs, which are high-cost drugs, to non-specialty-tier-eligible drugs to examine whether specialty-tier-eligible drugs had different price changes than non-specialty-tier-eligible drugs.[14] We considered specialty-tier-eligible drugs to be those drugs with a median cost that exceeded $600[15] for a 30-day supply in 2011 (see app. II for a list of the brand-name drugs considered specialty-tier-eligible).[16]

[12]After performing these data edits, and trimming the data, which resulted in the exclusion of about 4 percent of PDEs from our analysis, the average coefficient of variation (i.e., the standard deviation divided by the mean) for the ingredient cost per unit variable improved, decreasing from 23 to 3 percent.

[13]While 50 brand-name drugs overlapped the two baskets, each of these drugs had a different weight depending on their relative utilization in each basket.

[14]The basket of brand-name drugs used by beneficiaries who did not reach the coverage gap in 2011 did not include specialty-tier-eligible drugs.

[15]CMS establishes a minimum cost threshold that drugs must exceed before Medicare Part D plans can place them on a specialty tier, and in 2011 the threshold was $600.

[16]We calculated the cost based on the sum of the drug's ingredient cost, sales tax, dispensing fee, and vaccination fee, if applicable.

Our analyses of the trends in Medicare Part D prices are limited because we did not account for the multiple factors that can affect the prices of brand-name drugs over time. As a result, any changes we observed in prices may not be directly related to the implementation of the Discount Program. In addition, our analyses were limited to those brand-name drugs that had the highest total expenditures in 2011. We reviewed all data from CMS for reasonableness and consistency, including screening for outliers. We also reviewed documentation and talked to CMS officials about steps they take to ensure data reliability. We determined that these data were sufficiently reliable for our purposes.

Appendix II: Brand-Name Drugs Included in Price Trend Analyses

We analyzed the trend in Medicare Part D prices from January 2007 through December 2011 for two baskets of brand-name drugs used by beneficiaries who did not receive a low-income subsidy (LIS). Table 3 lists the drugs we analyzed for both baskets:

- the 27 high-expenditure brand-name drugs unique to the basket of drugs used by non-LIS beneficiaries in the coverage gap in 2011,
- the 28 high-expenditure brand-name drugs unique to the basket of drugs used by non-LIS beneficiaries who did not reach the coverage gap in 2011, and
- the 50 high-expenditure brand-name drugs that overlapped both drug baskets.

Table 3: The High-Expenditure Brand-Name Drugs Used by Non-LIS Beneficiaries in the Coverage Gap and by Those Who Did Not Reach the Coverage Gap in 2011

Drug name, strength, route of administration, and dosage form
27 High-Expenditure Brand-Name Drugs Unique to the Basket of Drugs Used by non-LIS Beneficiaries in the Coverage Gap in 2011
1. Atripla (600mg-200mg-300mg/oral/tablet)[a]
2. Avonex (30mcg/0.5ml/multiple routes/kit)[a]
3. Azilect (1mg/oral/tablet)
4. Enbrel (50mg/1ml/subcutaneous/solution)[a]
5. Enbrel (50mg/1ml/subcutaneous/solution)[a]
6. Femara (2.5mg/oral/tablet)
7. Gleevec (400mg/oral/tablet)[a]
8. Humalog (100u/1ml/subcutaneous/suspension)
9. Humalog MIX 75 25 (25u/1ml-75u/1ml/subcutaneous/suspension)
10. Humira[a,b]
11. Januvia (50mg/oral/tablet)
12. Levemir (100u/1ml/subcutaneous/solution)
13. Lyrica (50mg/oral/capsule)
14. Namenda (5mg/oral/tablet)
15. Novolog (100u/1ml/subcutaneous/solution)
16. Novolog FLEXPEN (100u/1ml/subcutaneous/solution)
17. Novolog MIX 70 30 (30u/1ml-70u/1ml/subcutaneous/suspension)
18. Novolog MIX 70 30 (30u/1ml-70u/1ml/subcutaneous/suspension)
19. Sensipar (30mg/oral/tablet)
20. Seroquel (25mg/oral/tablet)

Drug name, strength, route of administration, and dosage form
21. Seroquel (50mg/oral/tablet)
22. Seroquel (100mg/oral/tablet)
23. Tarceva (150mg/oral/tablet)[a]
24. Tracleer (125mg/oral/tablet)[a]
25. Zyprexa (5mg/oral/tablet)
26. Zyprexa (10mg/oral/tablet)
27. Zyprexa (2.5mg/oral/tablet)
28 High-Expenditure Brand-Name Drugs Unique to the Basket of Drugs Used by Non-LIS Beneficiaries Who Did Not Reach the Coverage Gap in 2011
1. Actonel (35mg/tablet/oral)
2. Alphagan P (0.1%/ophthalmic/solution)
3. Avapro (300mg/oral/tablet)
4. Avapro (150mg/oral/tablet)
5. Avelox (400mg/oral/tablet)
6. Azopt (0.1%/ophthalmic/suspension)
7. Benicar (20mg/oral/tablet)
8. Benicar HCT (25mg-40mg/oral/tablet)[c]
9. Benicar HCT (12.5mg-40mg/oral/tablet)[c]
10. Diovan HCT(25mg-160mg/oral/tablet)[c]
11. Diovan HCT(12.5mg-80mg/oral/tablet)[c]
12. Diovan HCT (12.5mg-320mg/oral/tablet)[c]
13. Flovent HFA (0.11mg/inhalation/aerosol)[d]
14. Humulin N (100u/1ml/subcutaneous/suspension)
15. Klor Con 10 (10mEq/oral/tablet(ER))[e]
16. Lumigan (0.03%/ophthalmic/solution)
17. Nasonex (0.05mg/nasal/spray)
18. Nevanac (0.10%/ophthalmic/solution)
19. Premarin (0.625mg/oral/tablet)
20. Premarin (0.3mg/oral/tablet)
21. Premarin vaginal (0.625mg/1gm/vaginal/cream)
22. Ventolin HFA (0.09mg/inhalation/aerosol)[d]
23. Vigamox (0.50%/ophthalmic/solution)
24. Vytorin (10mg-40mg/oral/tablet)
25. Vytorin (10mg-20mg/oral/tablet)
26. Vytorin (10mg-80mg/oral/tablet)
27. Xalatan (0.01%/ophthalmic/solution)
28. Zostavax (19400pfu/subcutaneous/powder)

Drug name, strength, route of administration, and dosage form
50 High-Expenditure Brand-Name Drugs that Overlapped the Basket of Drugs Used by Non-LIS Beneficiaries in the Coverage Gap in 2011 and the Basket of Drugs Used by Those Who Did Not Reach the Gap
1. Actos (30mg/oral/tablet)
2. Actos (45mg/oral/tablet)
3. Actos (15mg/oral/tablet)
4. Advair Diskus 100/50 (0.1mg-0.05m/inhalation/disk)
5. Advair Diskus 250/50 (0.25mg-0.0m/inhalation/disk)
6. Advair Diskus 500/50 (0.5mg-0.05m/inhalation/disk)
7. Aggrenox (25mg-200mg/oral/capsule(ER))[e]
8. Asacol (400mg/oral/tablet)
9. Avodart (0.5mg/oral/capsule)
10. Benicar (40mg/oral/tablet)
11. Boniva (150mg/oral/tablet)
12. Celebrex (200mg/oral/capsule)
13. Combivent (0.09mg-0.018mg/inhalation/aerosol)
14. Crestor (10mg/oral/tablet)
15. Crestor (20mg/oral/tablet)
16. Crestor (40mg/oral/tablet)
17. Crestor (5mg/oral/tablet)
18. Cymbalta (30mg/oral/capsule(DR))[f]
19. Detrol LA[g] (4mg/oral/capsule (ER))[e]
20. Diovan (160mg/oral/tablet)
21. Diovan (320mg/oral/tablet)
22. Diovan (80mg/oral/tablet)
23. Diovan HCT (25mg-320mg/oral/tablet)[c]
24. Diovan HCT (12.5mg-160mg/oral/tablet)[c]
25. Evista (60mg/oral/tablet)
26. Humulin 70 30 (70u/1ml-30u/1ml/subcutaneous/suspension)
27. Januvia (100mg/oral/tablet)
28. Lantus (100u/1ml/subcutaneous/solution)
29. Levemir (100u/1ml/subcutaneous/solution)
30. Lexapro (10mg/oral/tablet)
31. Lexapro (20mg/oral/tablet)
32. Lidoderm (5%/topical/patch (ER))[e]
33. Lipitor (20mg/oral/tablet)
34. Lipitor (40mg/oral/tablet)
35. Lipitor (10mg/oral/tablet)

Drug name, strength, route of administration, and dosage form
36. Lipitor (80mg/oral/tablet)
37. Lyrica (75mg/oral/capsule)
38. Namenda (10mg/oral/tablet)
39. Nexium (40mg/oral/capsule (DR))[f]
40. Plavix (75mg/oral/tablet)
41. Proair HFA (0.09mg/inhalation/aerosol)[g]
42. Restasis (0.05%/ophthalmic/emulsion)
43. Singulair (10mg/oral/tablet)
44. Spiriva (18mcg/inhalation/capsule)
45. Travatan Z (0.004%/ophthalmic/solution)
46. Tricor (145mg/oral/tablet)
47. Vesicare (5mg/oral/tablet)
48. Vesicare (10mg/oral/tablet)
49. Welchol (625mg/oral/tablet)
50. Zetia (10mg/oral/tablet)

Source: GAO analysis of 2007 to 2011 Prescription Drug Event Data from CMS and July 2011 Red Book data.

Notes: The drug strength indicates how much of the active ingredient is present in each dosage. The route of administration is the way of administering a drug to a site in a patient. The dosage form is the physical form in which a drug is produced and dispensed, such as a tablet, a capsule, or an injectable. Brand-name drugs were selected using the nine-digit national drug code (NDC-9). Levemir, Novolog MIX 70 30, and Enbrel are listed twice with the same strength, route of administration, and dosage form because each had two different NDC-9s.

[a]We characterized these drugs as specialty-tier-eligible drugs because they had a median cost that exceeded $600 for a 30-day supply in 2011. CMS establishes a minimum cost threshold that drugs must exceed before Medicare Part D plans can place them on a specialty tier, and in 2011 the threshold was $600.

[b]Humira is a biologic that comes as a solution that is injected. Biologics replicate natural substances such as enzymes, antibodies, or hormones, and according to the Food and Drug Administration, most biologics are complex mixtures that are not easily identified or characterized.

[c]HCT=hydrochlorothiazide.

[d]HFA=hydrofluoroalkanes.

[e]ER=extended release.

[f]DR=delayed release.

[g]LA=long acting.

Appendix III: How the Discount Program Works at the Point-of-Sale for Brand-Name Drugs

Under the Medicare Coverage Gap Discount Program (Discount Program), the plan-negotiated drug price is the price used in the calculation of the 50 percent discount for brand-name drugs.[1] The 50 percent discount is based on the sum of the plan-negotiated drug price and the drug's sales tax. This sum is called the discounted amount, and the beneficiary and manufacturer each pay 50 percent of the discounted amount. The beneficiary is also responsible for the drug's dispensing fee and vaccination fee, if applicable.[2] The entire cost of the drug, which includes the amount the beneficiary and manufacturer pays, is counted as out-of-pocket spending for the beneficiary, that is, towards the amount the beneficiary needs to move out of the coverage gap and into the catastrophic coverage period. Figure 4 provides a hypothetical example of how the 50 percent discount would be calculated at the point- of-sale for the purchase of a brand-name drug by a beneficiary who does not receive a low-income subsidy (non-LIS), is enrolled in a defined standard benefit plan in 2011, and has reached the coverage gap.

[1]42 U.S.C. § 1395w-114a(g)(6); 77 Fed. Reg. 22072, 22080, 22172 (Apr. 12, 2012) (to be codified at 42 C.F.R. § 423.2305).

[2]Both the dispensing and vaccination fees apply to the beneficiary's out-of-pocket spending. Beginning in 2013, CMS will require that beneficiaries be responsible for only a portion of the drug dispensing fee for all applicable drugs while they are in the coverage gap. This portion is commensurate with the beneficiary coinsurance (e.g., 47.5 percent coinsurance for brand-name drugs in 2013). The plan sponsor will be responsible for paying the remaining portion of the dispensing fee. CMS, *Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, at 32, (Apr. 2, 2012).

Figure 4: Hypothetical Example: A Non-LIS Beneficiary in a Standard Benefit Plan Purchasing a Brand-Name Drug While in the Coverage Gap in 2011

Example: Mrs. Jones reaches the coverage gap. She goes to her pharmacy to fill a prescription for a covered brand-name drug. The price of the drug is $95, the sales tax is $5, and the dispensing fee is $2. Once the 50 percent discount is applied, the cost of the drug is $50. Because the $2 dispensing fee is added to the discounted amount, Mrs. Jones will pay $52 for the prescription. The entire $102 will be counted as out-of-pocket spending, part of the total needed for Mrs. Jones to reach the catastrophic coverage limit and move out of the coverage gap.

Description of costs	Amount
Plan-negotiated drug price	$95.00
Drug's sales tax	$5.00
Drug's discounted amount = drug price + sales tax	$100.00
Drug's dispensing fee	$2.00
Mrs. Jones' total cost = 50 percent of discounted amount + dispensing fee	$52.00
Manufacturer's total cost = 50 percent of discounted amount	$50.00
Total amount applied to Mrs. Jones' out-of-pocket spending	$102.00

Source: GAO.

Note: The plan-negotiated drug price is the price that a plan sponsor, or pharmacy benefit manager on behalf of the plan sponsor, has negotiated for the beneficiary's plan.

Appendix IV: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

SEP 10 2012

John E. Dicken
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Dicken:

The Department appreciates the opportunity to review the U.S. Government Accountability Office's (GAO) report entitled, "MEDICARE PART D COVERAGE GAP: Discount Program Effects and Brand-name Drug Price Trends" (GAO 12-914).

As the report notes, the Centers for Medicare and Medicaid Services (CMS) implemented a comprehensive oversight strategy to manage the Discount Program. CMS will continue to manage this program aggressively to ensure that brand-name discounts are applied accurately and timely.

The GAO's findings from both the stakeholder interviews and the price stability analysis are consistent with HHS's expectations and experience. CMS's own analysis of pricing data using a different methodology resulted in similar findings. We will continue to monitor price stability for all Part D drugs and the impact of drug prices on the Part D program.

Sincerely,

Jim R. Esquea

Jim R. Esquea
Assistant Secretary for Legislation

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

John E. Dicken, (202) 512-7114 or DickenJ@gao.gov

Staff Acknowledgments

In addition to the contact named above, individuals making key contributions to this report include Rashmi Agarwal, Assistant Director; Zhi Boon; Robert Copeland; Pam Dooley; Seta Hovagimian; and Laurie Pachter.

Related GAO Products

Drug Pricing: Research on Savings from Generic Drug Use. GAO-12-371R. Washington, D.C.: January 31, 2012.

Prescription Drugs: Trends in Usual and Customary Prices for Commonly Used Drugs. GAO-11-306R. Washington, D.C.: February 10, 2011.

Medicare Part D: Spending, Beneficiary Out-of-Pocket Costs, and Efforts to Obtain Price Concessions for Certain High-Cost Drugs. GAO-10-529T. Washington, D.C.: March 17, 2010.

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.: January 29, 2010.

Brand-name Prescription Drug Pricing: Lack of Therapeutically Equivalent Drugs and Limited Competition May Contribute to Extraordinary Price Increases. GAO-10-201. Washington, D.C.: December 22, 2009.

Medicare Part D Prescription Drug Coverage: Federal Oversight of Reported Price Concessions Data. GAO-08-1074R. Washington, D.C.: September 30, 2008.

Prescription Drugs: Trends in Usual and Customary Prices for Drugs Frequently Used by Medicare and Non-Medicare Health Insurance Enrollees. GAO-07-1201R. Washington, D.C.: September 7, 2007.

Prescription Drugs: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004. GAO-05-779. Washington, D.C.: August 15, 2005.