

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**EFFECT OF THE PART D
COVERAGE GAP ON MEDICARE
BENEFICIARIES WITHOUT
FINANCIAL ASSISTANCE IN 2006**



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OBJECTIVES

1. To determine the number of Medicare beneficiaries who did not receive financial assistance with prescription drugs during the Part D coverage gap in 2006.
2. To determine changes in prescription drug purchases and payments by these beneficiaries.

BACKGROUND

Medicare Part D provides an optional drug benefit to Medicare beneficiaries. The Centers for Medicare & Medicaid Services (CMS) contracts with private insurance companies, known as plan sponsors, to provide prescription drug coverage for beneficiaries who choose to enroll in the program.

During the coverage year, the financial responsibilities of beneficiaries, plan sponsors, and CMS vary during each of four distinct coverage phases for the standard benefit: annual deductible, initial coverage, coverage gap, and catastrophic coverage. The coverage phase determines a beneficiary's share of the drug cost at the point of sale. After reaching the initial coverage limit, beneficiaries enter the coverage gap phase and are responsible for 100 percent of drug costs. Beneficiaries may receive financial assistance for drug costs during the coverage gap phase from their plans; from low-income subsidies; or from other approved third-party payers, such as State Pharmacy Assistance Programs.

We used Medicare Part D prescription drug data to determine the number of Medicare beneficiaries who did not receive financial assistance with prescription drug costs during the coverage gap in 2006. We also assessed beneficiary changes in drug purchasing behavior and payments during the coverage gap. Finally, we conducted a national beneficiary survey to further enhance our analysis of beneficiary changes in drug purchasing and use behaviors during the coverage gap.

FINDINGS

Seven percent of Part D beneficiaries entered the coverage gap and did not receive financial assistance with prescription drug costs. Of the more than 22 million Part D beneficiaries who filled at least one prescription in 2006, 1.5 million beneficiaries had gross covered drug

costs exceeding the initial coverage limit of \$2,250 and did not receive any financial assistance in paying for drugs during the coverage gap.

During the coverage gap, drug purchasing behavior changed for almost all beneficiaries who did not receive financial assistance.

Of the beneficiaries who did not receive financial assistance during the 2006 coverage gap, 98 percent made some changes in their drug purchasing behavior. Sixty-nine percent of beneficiaries decreased the average number of drugs purchased during the coverage gap. This decrease could have represented a strategy that beneficiaries used to reduce their financial burden during the coverage gap, or it could have represented appropriate reductions due to changes in their health status.

The greater the average number of drugs per month that beneficiaries purchased before entering the coverage gap, the more they reduced the average number of drugs per month that they purchased during the coverage gap. Beneficiaries who purchased an average of at least nine drugs per month had the largest decrease at 18 percent.

When a sample of beneficiaries similar to those included in the above analysis was surveyed, they identified specific types of changes in drug purchasing behavior and use. Thirty-eight percent of beneficiaries reported seeking at least one less-costly alternative to purchasing drugs. On the other hand, 20 percent of the beneficiaries surveyed may have been eligible for but not enrolled in a low-income subsidy that could have assisted them with purchasing drugs during the coverage gap. Additionally, one-third of the beneficiaries surveyed appeared to have compromised their drug regimens with changes in use.

RECOMMENDATIONS

CMS should support outreach and education activities targeted at beneficiaries who make more prescription drug purchases before entering the coverage gap. CMS could encourage plan sponsors to augment their outreach and education efforts by using drug utilization data to target beneficiaries who purchased nine or more drugs per month during the initial coverage phase. CMS could also supplement plan sponsors' outreach and education efforts by working directly with these beneficiaries to explore cost-saving strategies for prescription drugs and the tools available for choosing different benefit packages (in which they could enroll during the next open season).

CMS should target low-income subsidy outreach to beneficiaries who entered the coverage gap without financial assistance. Targeting the population of beneficiaries who entered the coverage gap without financial assistance in previous years might be one way to identify eligible beneficiaries for enrollment in the low-income subsidy program. In addition, beneficiaries who enter the coverage gap without financial assistance for prescription drug costs might benefit from more education about applying for the low-income subsidy that can assist them throughout the rest of the benefit year, including during the coverage gap.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS generally agreed with our findings and stated that it appreciated the additional information provided through the beneficiary survey. CMS noted that our findings were similar to the results of CMS's analysis presented at the Medicare Drug Benefit Symposium, held in October 2008. However, CMS indicated a concern about the lack of a control group with which to compare our results. As a result, CMS pointed out that this evaluation does not provide a true causal analysis. This is accurate, as the report does not present a true causal analysis. Rather, it presents data about drug purchases with a number of plausible explanations of those data, including the possibility that the decrease in drug purchases was the result of the coverage gap.

CMS did not concur with our first recommendation. CMS stated that it believed its current outreach to all beneficiaries is sufficient. However, we found that beneficiaries who made more prescription drug purchases before entering the coverage gap had the largest drop in the number of drugs purchased during the coverage gap. Because these beneficiaries take more prescription drugs, they are likely in poorer health and are the most vulnerable to negative health consequences from nonadherence to drug regimens. Therefore, additional outreach and education about efficient and effective drug purchasing options targeted at this group of beneficiaries could have far-reaching health benefits.

CMS concurred with our second recommendation. However, the actions CMS stated it would take do not address our recommendation to use drug utilization data to identify potential beneficiaries for the subsidy.

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OBJECTIVES

1. To determine the number of Medicare beneficiaries who did not receive financial assistance with prescription drugs during the Part D coverage gap in 2006.
2. To determine changes in prescription drug purchases and payments by these beneficiaries.

BACKGROUND

Research suggests that the Medicare Part D coverage gap may affect beneficiaries' prescription drug use behaviors. A 2006 national survey of noninstitutionalized Medicare beneficiaries found that rates of nonadherence to a drug regimen because of costs were greater for Part D beneficiaries than for seniors with the Veterans Administration or an employer-sponsored prescription drug plan.¹ The study suggested that beneficiaries who entered the Medicare Part D coverage gap may have changed their prescription drug use behaviors because they were responsible for 100 percent of their drug costs during the coverage gap.² Additional research suggests that Medicare beneficiaries whose benefits were capped use fewer prescription drugs overall and fewer drugs for treatment of chronic diseases.³

The Medicare Part D Prescription Drug Benefit

Medicare Part D provides an optional outpatient prescription drug benefit to Medicare beneficiaries.⁴ The Centers for Medicare & Medicaid Services (CMS) contracts with private entities, known as plan sponsors, to provide prescription drug coverage for beneficiaries who choose to enroll in the program. These plan sponsors may offer a stand-alone prescription drug plan or they may offer prescription drug coverage as part of a managed care plan, known as a Medicare Advantage prescription drug plan (hereinafter referred to collectively as plans).

¹ Patricia Neuman, et al., "Medicare Prescription Drug Benefit Progress Report: Findings From a 2006 National Survey of Seniors." *Health Affairs*, vol. 26, no. 5, August 21, 2007.

² *Ibid.*

³ John Hsu, et al., "Unintended Consequences of Caps on Medicare Drug Benefits." *The New England Journal of Medicine*, vol. 354, no. 22, June 1, 2006.

⁴ The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), P.L. No. 108-173 § 101, Social Security Act, § 1860D, 42 U.S.C. § 1395w-101(a).

Part D Coverage

During the coverage year, the financial responsibilities of beneficiaries, plan sponsors, and CMS vary during each of four distinct coverage phases for the standard benefit: annual deductible, initial coverage, coverage gap, and catastrophic coverage.⁵ The coverage phase determines a beneficiary's cost.⁶ In general, beneficiaries are responsible for a monthly premium; a deductible; and cost-sharing at the point of sale, which can be either percentage-based coinsurance or a fixed copayment.

To determine the coverage phase, plan sponsors must track prescription drug costs and payments every time a beneficiary fills a prescription under Part D. Cost data include the cost of the drug, dispensing fee, and sales tax. Payment data include all payments made by plan sponsors; beneficiaries; and other approved third-party payers, such as State Pharmacy Assistance Programs (SPAP).⁷

Part D Coverage Types

The MMA permits plan sponsors to offer plans with either standard prescription drug coverage or alternative prescription drug coverage.⁸ Alternative prescription drug coverage may be either actuarially equivalent to standard prescription drug coverage or enhanced.⁹ Plan benefits, including formularies, premiums, deductibles, and beneficiary cost-sharing requirements, vary according to coverage type.¹⁰

Standard coverage. In 2006, standard plans had an initial deductible of \$250.¹¹ In all standard plans, after paying the deductible, beneficiaries enter the initial coverage phase. During initial coverage, beneficiaries pay a 25-percent coinsurance toward Part D drug costs. Initial coverage continues until gross covered drug costs reach the initial coverage limit

⁵ CMS, "2007 Prescription Drug Event Data Training Participant Guide," Module 4 – Calculating and Reporting the Basic Benefit, p. 4-3, 2007.

⁶ Ibid.

⁷ Other approved third-party payers include health savings accounts, flexible spending accounts, medical savings accounts, and certain charities.

⁸ MMA, P.L. No. 108-173 § 101, Social Security Act, § 1860D, 42 U.S.C. § 1395w-102(a).

⁹ 42 CFR § 423.104(e) and (f).

¹⁰ MMA, P.L. No. 108-173 § 101, Social Security Act, § 1860D, 42 U.S.C. § 1395w-102(b) and (c).

¹¹ 42 CFR § 423.104(d)(1).

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established by law.¹² Gross covered drug costs are the total cost of drugs (including dispensing fee and sales tax) regardless of payer.

After reaching the initial coverage limit, beneficiaries in most plans enter the coverage gap phase and are responsible for 100 percent of drug costs. The coverage gap continues until beneficiaries' true out-of-pocket (TrOOP) spending reaches the annual TrOOP threshold.¹³ Generally, TrOOP spending includes all beneficiary payments (excluding monthly premiums) and any payments made by approved third-party payers.¹⁴

After reaching the TrOOP threshold, beneficiaries enter the catastrophic coverage phase. During catastrophic coverage, beneficiaries pay approximately 5 percent in coinsurance toward Part D drug costs,¹⁵ plans pay approximately 15 percent, and CMS pays plans the remaining 80 percent.

The maximum amount that beneficiaries pay out of pocket for the deductible and during the initial coverage and coverage gap phases are adjusted yearly.¹⁶ The 2006 standard coverage thresholds are shown in Table 1.

Table 1: 2006 Standard Coverage Cost-Sharing Thresholds by Benefit Phase

Benefit Phase	Gross Drug Costs	Cost-Sharing					
		Beneficiary		Plan		CMS	
		Maximum Total Cost*	Percentage of Drug Cost	Maximum Total Cost	Percentage of Drug Cost	Maximum Total Cost	Percentage of Drug Cost
Deductible	\$250	\$250	100%	\$0	0%	\$0	0%
Initial coverage	> \$250 to \$2,250	\$500	25%	\$1,500	75%	\$0	0%
Coverage gap	> \$2,250 to \$5,100	\$2,850	100%	\$0	0%	\$0	0%
Catastrophic coverage	generally > \$5,100	**	approximately 5%	**	15%	**	80%

* The beneficiary's maximum total cost does not include monthly premiums.
 ** The amount paid depends on the amount of drugs purchased during catastrophic coverage.

Source: "CMS 2007 Prescription Drug Event Data Training Participant Guide," 2007.

¹² MMA, P.L. No. 108-173 § 101, Social Security Act, § 1860D,

42 U.S.C. § 1395w-102(b)(3)(A).

¹³ 42 CFR § 423.104(d)(5)(iii).

¹⁴ CMS, "Prescription Drug Benefit Manual," ch. 5 § 30.

¹⁵ 42 CFR § 423.104(d)(5)(B).

¹⁶ 42 CFR § 423.104(d)(1)-(5).

Actuarially equivalent coverage. Actuarially equivalent plans offer coverage that is at least equal to the value of standard coverage.¹⁷ Actuarially equivalent plans may contain a coverage gap phase. However, they may increase the initial coverage limit, which could make the entry point into the coverage gap different from the entry point under standard coverage. Actuarially equivalent plans can also offer lower or no deductibles and copayments instead of coinsurance at the point of sale.

Enhanced coverage. Enhanced plans must provide supplemental benefits in addition to providing standard prescription drug coverage.¹⁸ As part of their supplemental benefits package, enhanced plans must offer coverage of drugs that are specifically excluded as Part D drugs or at least one feature that increases the value above the actuarial value of standard coverage.¹⁹ Features that can be used to increase the actuarial value of benefits include lower deductibles, an increase in the initial coverage limit, or reductions in cost sharing at the point of sale. Although enhanced plans may provide lower beneficiary cost-sharing obligations or full coverage during the coverage gap, most enhanced plans did not in 2006.

Part D Enrollment

In 2006, 22.5 million Medicare beneficiaries were enrolled in Part D plans.²⁰ Enrollment varied among coverage types: 17 percent of Part D beneficiaries were enrolled in standard coverage plans, 52 percent in actuarially equivalent coverage plans, and 30 percent in enhanced coverage plans.^{21 22}

¹⁷ MMA, P.L. No. 108-173 § 101, Social Security Act, § 1860D, 42 U.S.C. § 1395w-102(c)(1)(A).

¹⁸ 42 CFR § 423.104(f).

¹⁹ 42 CFR § 423.104(f)(1)(ii).

²⁰ The Henry J. Kaiser Foundation, "Medicare Data Update: Prescription Drug Coverage Among Medicare Beneficiaries," June 2006. Available online at <http://www.kff.org/medicare/upload/7453.pdf>. Accessed on August 1, 2008.

²¹ Juliette Cubanski, Patricia Neuman, "Status Report on Medicare Part D Enrollment in 2006: Analysis of Plan-Specific Market Share and Coverage," Health Affairs, 26, p. w6, 2007.

²² Percentages do not add to 100 percent because of rounding.

Part D Drugs

Covered Part D drugs are the subset of Part D drugs that are included on a Part D plan's formulary.²³ Part D excludes drugs for which payment is available under Medicare Parts A or B and drugs that may be excluded from coverage or otherwise restricted under Medicaid, except for smoking cessation agents.

Subject to a plan's formulary, Part D covers both generic and brand-name drugs. A generic drug is chemically identical to its brand-name counterpart, with the same therapeutic effect and risk-benefit profile. Generally, generic drugs are cheaper than brand-name drugs. According to the National Association of Chain Drug Stores, in 2006 the average brand-name prescription drug cost \$107.48, while the average generic prescription drug cost \$31.39—a 71-percent difference.²⁴ Although the use of generic drugs may help reduce costs, this reduction is possible only when a physician prescribes a generic drug or a pharmacist substitutes a generic drug if one is available for the prescribed brand-name drug.

Part D Low-Income Subsidy

To be eligible for a low-income subsidy, a beneficiary must meet an income and asset test. A beneficiary's annual income must be less than 150 percent of the Federal poverty level (FPL) (\$14,700 for an individual and \$19,800 for a married couple living together in 2006). The value of assets, including bank accounts, stocks, bonds, and real estate other than the beneficiary's primary residence, must be below \$10,000 for individuals and \$20,000 for married couples.

Beneficiaries with such limited income and assets are eligible to receive assistance to pay the out-of-pocket costs associated with their prescription drug coverage. The fewer financial resources an eligible beneficiary has, the lower his or her out-of-pocket costs will be in all coverage phases, including the coverage gap. Some beneficiaries receive drug coverage with no monthly premium, no annual deductible, and no copayments at the point of sale. Other beneficiaries pay copayments ranging from \$1 to \$5 but do not pay monthly premiums or annual

²³ Covered Part D drugs also include those that are on a Part D plan's formulary as a result of a coverage determination or appeal.

²⁴ National Association of Chain Drug Stores, "Industry Facts at a Glance: Pharmaceutical Pricing." Available online at <http://www.nacds.org/wmspage.cfm?parm1=507>. Accessed on June 6, 2008.

deductibles. Still other beneficiaries have a sliding-scale monthly premium, a \$50 deductible, and a coinsurance of 15 percent at the point of sale. Beneficiaries who receive the low-income subsidy are not subject to the coverage gap.

Previous Office of Inspector General Work

The Office of Inspector General (OIG) has conducted many studies related to Part D, including generic drug utilization in Part D,²⁵ identifying beneficiaries for the low-income subsidy,²⁶ CMS's tracking of beneficiaries' TrOOP costs,²⁷ and dual eligibles' transition from Medicaid to Medicare.²⁸

METHODOLOGY

Scope

This study explores the effect of the coverage gap on beneficiaries' drug purchases during 2006 by focusing on beneficiaries without financial assistance (i.e., from plans; low-income subsidies; or other approved third-party payers, such as SPAP). During the coverage gap, beneficiaries with financial assistance did not face the same financial burden related to purchasing prescription drugs as beneficiaries without financial assistance. Thus, our analysis excludes beneficiaries who had financial assistance during the coverage gap. In addition, this study included only Part D-covered drugs in our analysis, as only those purchases count toward the initial coverage limit and beneficiaries' TrOOP costs.

Data Sources

We used 2006 Prescription Drug Event (PDE) data to conduct this study. CMS requires plans providing prescription drug coverage to submit PDE data for payment purposes. Each drug event included in these data represents the dispensing of a drug or medical supply for the injection of insulin.

²⁵ OIG, "Generic Drug Utilization in the Medicare Part D Program," OEI-05-07-00130, November 2007.

²⁶ OIG, "Identifying Beneficiaries Eligible for the Medicare Part D Low-Income Subsidy," OEI-03-06-00120, November 2006.

²⁷ OIG, "Tracking Beneficiaries' True Out-of-Pocket Costs for the Part D Prescription Drug Benefit," OEI-03-06-00360, December 2007.

²⁸ OIG, "Dual Eligibles' Transition: Part D Formularies' Inclusion of Commonly Used Drugs," OEI-05-06-00090, January 2006.

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We used two drug data compendia to supplement the PDE data. For each claim, these compendia indicated whether the prescribed drug was a brand-name or generic drug and whether the drug was typically prescribed to treat a chronic or an acute condition.

In addition, we conducted a national survey of beneficiaries. Using the PDE data, we selected a simple random sample of 300 beneficiaries who had gross covered drug costs greater than the initial coverage limit of \$2,250. We excluded all beneficiaries with low-income subsidies or those who were enrolled in enhanced plans from our sample to remove beneficiaries who might have received assistance during the coverage gap. The survey was distributed by mail in February 2008 and data collection lasted through March 2008.

Upon receiving the surveys, we removed beneficiaries who appeared to have received financial assistance during the coverage gap. We used 2006 PDE data to determine which beneficiaries did not pay 100 percent of their drug costs during the coverage gap. After removing any beneficiary who did not pay 100 percent of drug costs, we had a sample of 176 beneficiaries. Of these 176 beneficiaries, 142 responded to our survey, for an 81-percent response rate.

Because the survey was conducted in 2008, beneficiaries may have also been in the coverage gap in 2007. Therefore, we asked beneficiaries about their general experiences while in the coverage gap and did not ask them to tie their experiences to a specific year. The survey asked beneficiaries to identify, from predetermined lists of options, changes they made in how they used and purchased prescription drugs after entering the coverage gap. It also requested information such as marital status and income range.

For a complete list of the data sources and other aspects of the methodology, see Appendix A. For a copy of the beneficiary survey and for the total responses, see Appendix B.

Data Analysis

Determining the number of beneficiaries in the coverage gap. To establish how many beneficiaries entered the coverage gap and did not have financial assistance, we summed the appropriate cost and payment fields in the PDE data for Part D-covered drugs to determine which beneficiaries had gross covered drug costs exceeding the initial coverage limit. After identifying this population of beneficiaries, we selected all of their 2006 PDE claims for Part D-covered drugs (hereinafter referred to as drugs). Using the date when each beneficiary entered the coverage

gap and the date each became eligible for catastrophic coverage (if applicable), each claim was assigned to the proper coverage phase for that beneficiary: initial coverage (including deductible phase), coverage gap, and catastrophic coverage.²⁹ We then excluded beneficiaries who did not pay 100 percent of their drug costs during the coverage gap to remove beneficiaries who had financial assistance in the coverage gap.

Using these claims data, we calculated a number of descriptive measures. We determined the average number of days it took beneficiaries to enter the coverage gap, how long they remained in the coverage gap, and when they left the coverage gap for catastrophic coverage.

Analyzing changes in beneficiary drug purchases. To measure prescription drug purchasing in each coverage phase, we calculated three measures: (1) average number of prescription drugs purchased per month, (2) percentage of prescription drugs purchased to treat chronic and acute conditions, and (3) generic drug utilization rate.

To calculate the average number of prescription drugs purchased per month by coverage phase, we calculated the unique number of drugs by beneficiary by month. Then, for each coverage phase, we divided the total number of unique drugs by beneficiary by the total number of months.

For purposes of this analysis, in all prescription data, we normalized the data by the number of days that the prescription covered. We considered PDE data with a supply of less than or equal to 44 days as one prescription; greater than 44 days but less than or equal to 74 days as two prescriptions; and greater than 74 days as three prescriptions.

Analyzing changes in beneficiary drug payments. To analyze payment in each coverage phase, we computed the average and median beneficiary payment per phase and the average beneficiary payment per month. To determine the average and median beneficiary payment per phase, we used the PDE data field “patient pay amount” for each beneficiary. “Patient pay amount” is the amount that the beneficiary paid for each drug. We calculated the average beneficiary payment per month by

²⁹ For purposes of this analysis, the deductible and initial coverage phases were combined.

dividing the total beneficiary payment by the total number of months in that phase.

Analyzing beneficiary survey responses. To analyze beneficiary survey responses, we calculated basic frequencies on the key questions related to beneficiaries' changes in drug purchases and use during the coverage gap. We conducted a nonresponse analysis to see how our survey estimates might be affected by potential nonresponse bias and found no evidence of bias. Appendix C provides details of the nonresponse analysis.

We projected all survey statistics to beneficiaries who entered the coverage gap, were not enrolled in enhanced plans, did not receive low-income subsidies, and paid 100 percent of drug costs during the coverage gap based on their 2006 PDE claims. See Appendix D for a list of 95-percent confidence intervals for all statistical projections.

Data Limitations

Our analysis of PDE data covered only prescription drugs purchased through Part D. Because PDE data do not capture prescription drug purchases outside Part D, we could not capture the full extent of beneficiaries' prescription drug purchases. In addition, SPAP assistance with prescription drug costs would only have been visible in the PDE data if the SPAP coordinated with Part D. However, our survey analysis asked beneficiaries about the use of free medication samples and purchases made outside their Part D plans in an attempt to gather this information.

Because we chose to base our analysis of the PDE data on the number of months in which beneficiaries filled a prescription, not enrollment months, our results are not comparable to standard industry per-member-per-month measures, which are based on enrollment months. For example, our analysis of the average number of drugs per month may be higher than industry averages. However, this analytic choice does not change the relative decrease in the average number of drugs purchased per month after entering the coverage gap.

The population to which we project our survey sample is different from the population used to conduct the PDE analysis. Both populations excluded beneficiaries who received financial assistance during the coverage gap. The survey population, however, excluded all beneficiaries enrolled in enhanced plans, some of whom may not have received assistance during the coverage gap. In other words, the survey population, because of the means used to target beneficiaries, may not

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represent all beneficiaries who did not receive assistance during the coverage gap.

Standards

This study was conducted in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

Seven percent of Part D beneficiaries entered the coverage gap and did not receive financial assistance with their prescription drug costs

Of the 22 million Part D beneficiaries who filled at least one prescription in 2006, 7 percent had gross covered drug costs exceeding

the initial coverage limit of \$2,250 and did not receive any financial assistance during the coverage gap. This represents approximately 1.5 million beneficiaries. In contrast, 26 percent, or approximately 5.6 million beneficiaries, had gross covered drug costs exceeding the initial coverage limit but had some assistance during the coverage gap. This assistance could have come from their plans; low-income subsidies; or other approved third-party payers, such as SPAP. In total, 33 percent of beneficiaries had gross covered drug costs exceeding the initial coverage limit in 2006.

Time spent before the coverage gap. Beneficiaries who did not have financial assistance during the coverage gap took an average of 7 months to enter the coverage gap. In fact, 36 percent entered the coverage gap in the third quarter of the year, and 45 percent entered the coverage gap in the fourth quarter. Thirteen percent of beneficiaries who did not have assistance during the coverage gap entered the coverage gap in December.

Time spent in the coverage gap. Most beneficiaries who did not have financial assistance (83 percent) spent less than 6 months in the coverage gap. Approximately 17 percent spent 6 to 8 months in the coverage gap, and less than 1 percent spent 9 to 12 months.

Money spent during the coverage gap. While in the coverage gap, beneficiaries who did not have financial assistance spent an average total of \$979, with a median total of \$675. On average, these beneficiaries spent \$108 per month before entering the coverage gap and \$290 per month during the coverage gap.

Beneficiaries who left the coverage gap. Twelve percent (178,717) of beneficiaries without financial assistance during the coverage gap left it and entered catastrophic coverage. Beneficiaries who entered catastrophic coverage spent an average of 4.5 months in the coverage gap and 2.7 months in catastrophic coverage. Overall, 59 percent of beneficiaries who entered catastrophic coverage did so in the last quarter of 2006.

During the coverage gap, drug purchasing behavior changed for almost all beneficiaries who did not receive financial assistance

Of the beneficiaries who did not receive financial assistance during the 2006 coverage gap, 98 percent

made some changes in their drug purchasing behavior. During the coverage gap, 69 percent of beneficiaries decreased the average number of drugs purchased, while 29 percent increased the average number of drugs purchased.

For those beneficiaries who decreased the average number of drugs they purchased during the coverage gap, the number dropped from an average of 4.5 drugs per month to 3.8 drugs per month. This decrease could represent a strategy that beneficiaries used to reduce their financial burden during the coverage gap, when they were responsible for 100 percent of drug costs. This explanation is consistent with research suggesting that beneficiaries decrease prescription drug use when they encounter a gap in coverage. The decrease could also reflect nonadherence to prescribed drug regimens. On the other hand, the reduction could be the result of medically appropriate changes in beneficiaries' drug regimens due to changes in health status.

For those beneficiaries who increased the average number of drugs they purchased, the number rose from an average of 4.3 drugs per month to 5.6 drugs per month during the coverage gap. This increase is most likely explained by changes in the beneficiaries' drug regimens due to changes in health status.

Overall, changes in drug purchasing behavior did not alter the type of drugs purchased as measured by chronic versus acute drugs. Beneficiaries used chronic and acute drugs in the same proportions before and during the coverage gap, at a rate of approximately 80-percent chronic and 20-percent acute drugs. The high percentage of drugs that beneficiaries purchased to treat chronic conditions indicates that beneficiaries' prescription drug needs remain mostly stable over time, regardless of purchasing patterns. Because the percentage of acute drugs did not decrease during the coverage gap, the decrease in the average number of drugs is likely not explained by the cessation of acute medical conditions.

In addition, beneficiaries increased their utilization rate of generic drugs by 8 percent during the coverage gap, from 49 to 53 percent. Although the generic utilization rate increased during the coverage gap,

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it remained lower than the 2006 Part D national generic utilization rate of 56 percent.³⁰

Beneficiaries with more drug purchases before entering the coverage gap made greater changes in their drug purchasing behavior during the coverage gap

The greater the average number of drugs per month that beneficiaries purchased before entering the coverage gap, the more they reduced the average number of drugs per month that they purchased during the coverage gap. Beneficiaries who purchased an average of 1 to 4.9 drugs per month had a 9-percent decrease in the average number of drugs purchased per month, while beneficiaries who purchased an average of 5 to 8.9 drugs had a 10-percent decrease. Beneficiaries who purchased an average of at least nine drugs per month had the largest decrease, at 18 percent. See Table 2 for the changes in average monthly drug purchasing for all beneficiaries.

Beneficiaries by Average Drugs Purchased per Month Before Entering the Coverage Gap	Number of Beneficiaries	Average Monthly Number of Drugs Purchased Before Entering the Coverage Gap	Average Monthly Number of Drugs Purchased During the Coverage Gap	Percent Change
Beneficiaries purchasing 1–4.9 drugs	959,075	3.5	3.2	-9%
Beneficiaries purchasing 5–8.9 drugs	527,738	6.2	5.6	-10%
Beneficiaries purchasing 9 or more drugs	43,975	10.1	8.3	-18%

Source: OIG analysis of 2006 PDE data, 2008.

The greater the average number of drugs per month that beneficiaries purchased before entering the coverage gap, the greater their average monthly payments both before and during the coverage gap. However, beneficiaries who purchased an average of nine or more drugs per month before entering the coverage gap had a smaller percentage increase in their average monthly payments when comparing costs before and after entering the coverage gap than beneficiaries who purchased, on average, fewer drugs per month. See Table 3 for the changes in average monthly payments for all beneficiaries.

³⁰ OIG, “Generic Drug Utilization in the Medicare Part D Program,” OEI-05-07-00130, November 2007.

Table 3: Average Payment per Beneficiary per Month				
Beneficiaries by Average Drugs Purchased per Month Before Entering the Coverage Gap	Number of Beneficiaries	Average Monthly Payment Before Entering the Coverage Gap	Average Monthly Payment During the Coverage Gap	Percent Change
Beneficiaries purchasing 1–4.9 drugs	959,075	\$100	\$258	158%
Beneficiaries purchasing 5–8.9 drugs	527,738	\$120	\$319	166%
Beneficiaries purchasing 9 or more drugs	43,975	\$181	\$432	139%

Source: OIG analysis of 2006 PDE data, 2008.

Beneficiaries who purchased an average of nine or more drugs per month saw a 139-percent increase in average monthly payments compared to more than 150 percent for other beneficiaries. This smaller percentage increase is likely explained by the fact that this group of beneficiaries most dramatically reduced the average number of drugs purchased during the coverage gap, thereby mitigating the full financial burden of the coverage gap.

The smaller percentage increase is not explained by a change in generic drug utilization. In fact, the more drugs beneficiaries purchased on average before the coverage gap, the less likely that they were to increase their utilization of generic drugs during the coverage gap. Beneficiaries purchasing an average of 1 to 4.9 drugs per month increased their generic utilization rate from 44 percent before entering the coverage gap to 49 percent during the coverage gap. However, beneficiaries who purchased an average of five or more drugs per month before entering the coverage gap did not change their generic utilization rates. See Table 4 for rates of generic utilization before and during the coverage gap.

F I N D I N G S

Table 4: Rates of Generic Utilization				
Beneficiaries by Average Drugs Purchased per Month Before Entering the Coverage Gap	Number of Beneficiaries	Generic Utilization Rate Before Entering the Coverage Gap	Generic Utilization Rate During the Coverage Gap	Percent Change
Beneficiaries purchasing 1–4.9 drugs	959,075	44%	49%	11%
Beneficiaries purchasing 5–8.9 drugs	527,738	55%	55%	0%
Beneficiaries purchasing 9 or more drugs	43,975	59%	59%	0%

Source: OIG analysis of 2006 PDE data, 2008.

For the beneficiaries who purchased an average of five or more drugs per month before the coverage gap, increasing generic utilization rates may not have been an option. Their generic utilization rates before they entered the coverage gap were already higher than those of other beneficiaries. Further, their generic utilization rate was at or above the Part D national generic utilization rate.³¹

Although decreasing the average number of drugs that beneficiaries purchased during the coverage gap may have helped them reduce their financial burden, it may have kept them in the coverage gap longer. For example, beneficiaries who purchased an average of nine or more drugs per month before the coverage gap spent an average of 4.5 months in the coverage gap, compared to 4 months or less for other beneficiaries. See Table 5 for the average amount of time before beneficiaries entered the coverage gap and the average amount of time beneficiaries spent in the coverage gap.

Table 5: Average Time in the Coverage Gap in Months			
Beneficiaries by Average Drugs Purchased per Month Before Entering the Coverage Gap	Number of Beneficiaries	Average Amount of Time To Enter the Coverage Gap	Average Amount of Time in the Coverage Gap
Beneficiaries purchasing 1–4.9 drugs	959,075	7.9	3.0
Beneficiaries purchasing 5–8.9 drugs	527,738	6.8	4.0
Beneficiaries purchasing 9 or more drugs	43,975	4.5	4.5

Source: OIG analysis of 2006 PDE data, 2008.

³¹ OIG, “Generic Drug Utilization in the Medicare Part D Program,” OEI-05-07-00130, November 2007.

FINDINGS

Beneficiaries who purchased an average of nine or more drugs per month were possibly in the coverage gap longer, on average, than other beneficiaries. Because these beneficiaries purchased a greater average number of drugs per month, they entered the coverage gap earlier than other beneficiaries. It took this group of beneficiaries approximately 4.5 months to enter the coverage gap, compared to over 6.5 months for other beneficiaries. Thus, they had a longer time to spend in the coverage gap. Beneficiaries who entered the coverage gap later in the coverage year may have had their time in the coverage gap cut short by the end of the benefit year.

Surveyed beneficiaries identified specific types of changes in drug purchasing behavior and use

Changes in drug purchasing. When we surveyed a sample of beneficiaries similar to those included in the analysis above,³² 38 percent of the beneficiaries reported seeking at least one less-costly alternative to purchasing drugs, including free medication samples, comparison shopping, and switching to mail-order pharmacies. Table 6 lists changes that beneficiaries reported making in drug purchasing behavior during the coverage gap.

Table 6: Beneficiaries' Reported Changes in Drug Purchasing During the Coverage Gap

Changes in Purchasing Prescription Drugs	Percentage of Beneficiaries*
Used free medication samples	25%
Shopped around and compared prices	23%
Switched to a mail-order pharmacy	11%
Purchased drugs outside their plan	8%
*Choices are not mutually exclusive	

Source: OIG analysis of beneficiary survey responses, 2008.

In addition to seeking less-costly alternatives to purchasing prescription drugs, beneficiaries sought help from informal sources to help pay for drug purchases. Fifteen percent of beneficiaries who reported entering the coverage gap reported receiving help to pay for their prescription

³² For a discussion of the sampling methodology used to select this sample of beneficiaries, please see the methodology, p. 7.

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drug purchases during the coverage gap; 2 percent reported more than one type of help. Table 7 lists sources that beneficiaries reported receiving help from during the coverage gap.

Table 7: Beneficiaries' Reported Sources of Financial Help During the Coverage Gap	
Sources of Financial Assistance	Percentage of Beneficiaries
Family member or friend	8%
SPAP*	4%
Private pharmaceutical company	4%
Charitable organization	1%
*We removed all beneficiaries who received financial assistance during the 2006 coverage gap based on 2006 PDE data. This would include assistance from SPAPs. Beneficiaries may be referring to help from SPAPs in the 2007 coverage gap or may be confusing premium assistance with help paying for drugs at the point of sale.	

Source: OIG analysis of beneficiary survey responses, 2008.

Twenty percent of the beneficiaries surveyed may have been eligible for but not enrolled in a low-income subsidy that could have assisted them with purchasing prescription drugs during the coverage gap. These beneficiaries reported annual incomes below 150 percent of the FPL and therefore met the income eligibility requirements for a low-income subsidy; whether they would have passed the asset test as well is unknown.

Changes in drug use. Surveyed beneficiaries also identified changes in the ways in which they used prescription drugs. One-third appeared to have compromised their drug regimens, indicating that they used medications less often, stopped taking medications, or did not start new medications. In addition, 20 percent reported not consulting a medical professional before making changes to their drug regimens. Table 8 lists changes that beneficiaries reported making in the way they used prescription drugs during the coverage gap.

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Table 8: Beneficiaries' Reported Changes in Drug Use During the Coverage Gap

Changes in Prescription Drug Use	Percentage of Beneficiaries*
Used a medication less often than prescribed	21%
Switched to a different prescription drug	18%
Stopped taking one or more medications	16%
Did not start a new medication	14%
Switched to an over-the-counter drug	4%
*Choices are not mutually exclusive	

Source: OIG analysis of beneficiary survey responses, 2008.



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Seven percent of beneficiaries entered the coverage gap without financial assistance. Almost all of these beneficiaries made changes in their drug purchasing behavior during the coverage gap. In particular, 69 percent decreased the number of drugs that they purchased. In addition, the more drugs per month that beneficiaries purchased before entering the coverage gap, the more they reduced the number of drugs per month that they purchased during the coverage gap.

When surveyed, beneficiaries identified specific changes in the ways they purchased or used drugs during the coverage gap. Thirty-eight percent reported seeking at least one less-costly alternative to purchasing drugs, and one-third appeared to have compromised their drug regimens, potentially compromising their health.

Given that some beneficiaries appeared to decrease the number of drugs that they purchased during the coverage gap and the potential health consequences of those actions, we make the following recommendations to CMS:

CMS Should Support Outreach and Education Activities Targeted at Beneficiaries Who Make More Prescription Drug Purchases Before Entering the Coverage Gap

CMS could accomplish this by encouraging plan sponsors to augment their current outreach and beneficiary education efforts. CMS could encourage sponsors to use drug utilization data to target beneficiaries who purchase more drugs per month during initial coverage for more education about efficient and effective drug purchasing options. Medication Therapy Management programs (MTMP) could be expanded to discuss drug purchasing options and strategies.

CMS could also supplement plans' outreach and education efforts by working directly with beneficiaries who historically have purchased more drugs per month during initial coverage. These beneficiaries could be targeted using the previous year's PDE data. CMS could start by targeting beneficiaries who purchased nine or more drugs per month during initial coverage; our analysis shows that they had the most dramatic drop in the number of drugs purchased monthly during the coverage gap.

CMS could educate beneficiaries who purchased more drugs during initial coverage about cost-saving strategies for purchasing prescription drugs. This could include such strategies as talking to a doctor about switching to lower-cost, therapeutically equivalent drugs or comparison shopping to get the lowest prices on current drugs.

In addition, CMS could provide targeted education to these beneficiaries about the various tools available for choosing the most cost-effective prescription drug plan for the next year. Given that beneficiaries who purchased more drugs during initial coverage had a high rate of generic utilization, changing beneficiary purchasing behaviors within the same plan, in some cases, may not be enough to reduce the financial burden during the coverage gap.

CMS Should Target Low-Income Subsidy Outreach to Beneficiaries Who Entered the Coverage Gap Without Financial Assistance

Targeting the population of beneficiaries who entered the coverage gap without financial assistance in previous years might be one way to identify eligible beneficiaries for enrollment in the low-income subsidy program; 20 percent of the beneficiaries surveyed may have been eligible. As a 2006 OIG report demonstrates, there is no effective way to identify the pool of beneficiaries who may be eligible for the subsidy.³³ That report concluded that legislation is needed to allow CMS and the Social Security Administration to more effectively identify beneficiaries who are potentially eligible for the subsidy. We continue to support this conclusion.

In addition, CMS should continue targeting beneficiaries to promote the low-income subsidy and assist eligible beneficiaries. Beneficiaries who enter the coverage gap without financial assistance for prescription drug costs might benefit from more education about the low-income subsidy that can assist them throughout the rest of the benefit year.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS generally agreed with our findings and stated that it appreciated the additional information provided through the beneficiary survey. CMS noted that our findings were similar to the results of CMS's analysis presented at the Medicare Drug Benefit Symposium, held in October 2008. For example, we found that 7 percent of beneficiaries entered the coverage gap and did not receive financial assistance with their prescription drug costs. CMS found that almost 10 percent of beneficiaries who did not have a low-income subsidy and were not in a plan with gap coverage reached their plan's specific initial coverage

³³ OIG, "Identifying Individuals Eligible for the Medicare Part D Low-Income Subsidy," OEI-03-06-00120, November 2006.

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limit. The difference in results can be explained by different analytic approaches, as CMS correctly noted.

Although CMS generally agreed with our findings, it indicated a concern about the lack of a control group with which to compare our results. As a result, CMS pointed out that this evaluation does not provide a true causal analysis. This is accurate, as the report does not present a true causal analysis. Rather, it presents data about drug purchases with a number of plausible explanations of those data, including the possibility that the decrease in drug purchases was the result of the coverage gap. This explanation is consistent with research described in the body of the report suggesting that beneficiaries decrease prescription drug use when they encounter a gap in coverage.

In addition, CMS questioned whether the decrease in drug purchases could be attributed to the coverage gap. CMS stated that it had conducted a similar analysis using beneficiaries who received a low-income subsidy as a comparison group. CMS found that the comparison group decreased the number of drugs purchased per month despite the fact that they did not face a coverage gap. However, it is unclear whether the extent of the decrease was as sharp for this group as it was for beneficiaries without financial assistance during the coverage gap.

In response to our recommendation that CMS support outreach and education activities targeted at beneficiaries who make more prescription drug purchases before entering the coverage gap, CMS stated that it believed its current outreach to all beneficiaries is sufficient. CMS stated that the annual open-enrollment campaign encourages all beneficiaries to make informed decisions based on cost. In addition, CMS indicated that the Medicare Prescription Drug Plan Finder tool selects generic alternatives as the default and can substitute lower-cost therapeutic alternatives. Thus, beneficiaries can use this tool to explore cost-saving options. Lastly, CMS highlighted the additional outreach done through Part D sponsors and their MTMPs.

However, we found that beneficiaries who made more prescription drug purchases before entering the coverage gap had the largest drop in the number of drugs purchased during the coverage gap. Because these beneficiaries take more prescription drugs, they are likely in poorer health and are the most vulnerable to negative health consequences from nonadherence to drug regimens. Therefore, additional outreach and education about efficient and effective drug purchasing options

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targeted at this group of beneficiaries could have far-reaching health benefits. Current CMS outreach and plan sponsor MTMPs do not target this group, nor are MTMPs required to assist with financial decisions or provide cost-saving strategies.

CMS concurred with our second recommendation that CMS target low-income subsidy outreach to beneficiaries who entered the coverage gap without financial assistance. CMS indicated that it would continue to emphasize the financial value of the low-income subsidy to attract beneficiaries with significant drug utilization who might benefit from the subsidy. However, this action does not address our recommendation, which is to use drug utilization data to identify potential beneficiaries for the subsidy. Given the recognized difficulty in identifying beneficiaries who may be eligible for the subsidy, we offered this as an additional approach.

CMS also offered a few technical comments. They offered the same comments when asked to informally comment on the draft report. We did not alter our draft report in response to these comments because they primarily pointed out how our analysis is different from other approaches. Given that we clearly stated our approach, this did not seem necessary. For this final version of the report, we have sought to make these differences explicit. For the full text of CMS's comments, see Appendix E.

Detailed Methodology

This study explores the effect of the coverage gap on beneficiaries' drug purchasing behavior by focusing on those beneficiaries without assistance during the coverage gap in 2006. We examined changes in drug purchasing behavior and costs for these beneficiaries as they moved from initial coverage into the coverage gap.

Data Sources

We used 2006 Prescription Drug Event (PDE) data to conduct this study. The Centers for Medicare & Medicaid Services (CMS) requires plans providing prescription drug coverage to submit PDE data for payment purposes. Each drug event included in the PDE data represents the dispensing of a drug or medical supply for the injection of insulin. These data contain the beneficiary's identification number; the Food and Drug Administration's National Drug Code (NDC);³⁴ the date of service; the number of days for which the drug is supplied; and payments at point of sale made by plan sponsors, beneficiaries (or on behalf of beneficiaries), and other approved third-party payers. Our analysis included final action PDE claims submitted by all plans for 2006 as of July 2007.³⁵

We used two drug data compendia to supplement the PDE data: (1) August 2007 First DataBank drug product information data and (2) first quarter 2007 Redbook drug product data. The 2007 First DataBank and Redbook data contained information on all drugs covered by Part D in 2006 but with more up-to-date drug information than earlier versions of First DataBank and Redbook. First DataBank is a database containing drug product information, such as drug name and therapeutic class, for each NDC. Redbook is a database that provides pricing and descriptive information for prescription and over-the-counter drugs.

³⁴ An NDC is a three-part universal identifier that specifies the manufacturer, product, and package size.

³⁵ Final action claims are those that CMS uses to reconcile payments to plans. A PDE record is submitted each time a beneficiary fills a prescription covered under Part D. The PDE records may be amended or deleted up to 6 months after the end of the payment year. After that point, CMS considers them to be final action claims.

In addition, we conducted a national survey of a random sample of beneficiaries. We used the Medicare enrollment database to obtain addresses for our sample and public directories to find phone numbers.

To ensure the construct validity of our cover letter and survey instrument, we conducted two focus group meetings at senior centers. We asked beneficiaries to read the cover letter and complete the survey. After they completed the survey, we conducted brief cognitive interviews to determine whether the cover letter and survey were clear and understandable. Most beneficiaries interpreted the survey questions as we intended. Where necessary, we altered the survey based on the feedback we received from the focus groups to make it more understandable.

We conducted the survey primarily by mail. For beneficiaries with valid phone numbers, we made three attempts by mail and two attempts by phone to obtain their responses. For beneficiaries without valid phone numbers, we made five mail attempts.

We allowed proxy respondents. We asked that the person who made health care decisions on behalf of the beneficiary complete the survey. Approximately 23 percent of the surveys were completed by someone other than the beneficiary.

Data Analysis

Determining the number of beneficiaries in the coverage gap. The complete final action 2006 PDE data contained nearly 817 million claims for over 22 million beneficiaries. To obtain our population of beneficiaries who had gross covered drug costs exceeding the initial coverage limit and did not have financial assistance, we completed a series of steps.

First, we removed some claims:

1. We excluded all claims for noncovered Part D drugs because these claims do not count toward true out-of-pocket expenses. This removed 5,889,021 claims from the PDE data, representing less than 1 percent of the total claims.
2. We removed claims without corresponding drug-identifying information. We merged beneficiary claims with First DataBank and Redbook data. This removed 166,405 claims because the drugs were not listed in at least one of those data sources.

Then, we determined our population:

1. We removed all beneficiaries who did not have gross covered drug costs greater than the initial coverage limit of \$2,250. To do this, we calculated cumulative and total spending for each beneficiary using these PDE data fields: ingredient cost, dispensing fee, and sales tax. This removed 14,783,703 beneficiaries, representing 66.7 percent of all beneficiaries.
2. We then removed all beneficiaries who received assistance from a low-income subsidy. To complete this step, we used the PDE data field that records the amount of a beneficiary's low-income subsidy, if any. If this field was greater than zero, we removed the beneficiary. This removed 4,257,527 beneficiaries, representing 19.2 percent of all beneficiaries.
3. Finally, we removed all beneficiaries who did not pay 100 percent of the drug's ingredient cost, dispensing fee, and sales tax for all claims during the coverage gap. To do this, we separated the claims into three phases: (1) before the coverage gap, which included both the deductible and initial coverage; (2) during the coverage gap; and (3) catastrophic coverage (after the coverage gap). We then determined which beneficiaries had claims during the coverage gap for which they did not pay 100 percent of the drug cost. This removed 1,411,446 beneficiaries, representing 6.4 percent of all beneficiaries.

We assumed the standard 2006 initial coverage limit of \$2,250 as the threshold for entry into the coverage gap. While we did not use the initial coverage limit specific to each beneficiary's plan, we did exclude all forms of assistance in the coverage gap, which includes additional assistance from plans with extended initial coverage limits.

Finally, we removed additional beneficiaries because of data anomalies that made their claims history implausible:

1. We removed any beneficiary whose entry into catastrophic coverage preceded his or her entry into the coverage gap. To do this, we calculated the date when each beneficiary entered the coverage gap and catastrophic coverage. An additional 16,808 beneficiaries were removed in this step, representing less than 1 percent of all beneficiaries.

2. We removed any beneficiary who had a claim before the coverage gap but not during it or who had a claim during the coverage gap but not before. This removed an additional 166,017 beneficiaries, representing less than 1 percent of all beneficiaries.

As a result, our population consisted of 1,530,788 beneficiaries with 81,922,129 claims. We assigned beneficiaries to one of three groups, based on the average number of drugs purchased per month during initial coverage: 1 to 4.9 drugs, 5 to 8.9, and 9 or more. This allowed us to analyze changes in drug purchasing and payment across groups, based on the average number of drugs purchased.

Analyzing changes in beneficiary drug purchases. To measure drug purchasing in each coverage phase, we calculated three measures: (1) average number of different drugs per month, (2) percentage of drugs purchased to treat chronic and acute conditions, and (3) generic drug utilization rate.

We based our count of drugs per beneficiary on the Ingredient List Identifier for each drug. This represents a unique combination of active ingredients, regardless of manufacturer, package size, dosage form, route of administration, or strength. As such, it incorporates multiple NDCs.

Where we refer to months in our calculations, we calculated months based on the whether or not a beneficiary filled a prescription. If a beneficiary had a claim during a given month, we counted that calendar month towards his or her total months.

To identify the percentage of chronic and acute drugs purchased per phase, we used a data field from the Redbook that indicated, at the NDC level, whether a drug was considered to be a maintenance drug. Maintenance drugs are used to treat chronic conditions. In each coverage phase, we counted the total number of maintenance and nonmaintenance drugs prescribed and divided that by the total number of drugs purchased.

To identify the generic drug utilization rate per phase, we used a data field from First DataBank that indicates, at the NDC level, whether a drug is a brand-name or generic drug. We then identified the number of prescriptions labeled as generic for each beneficiary.

Beneficiary Survey Responses

THIS SURVEY SHOULD TAKE YOU ABOUT 15 MINUTES TO COMPLETE. PLEASE INDICATE YOUR ANSWER BY CHECKING THE CORRECT BOX.

A FEW QUESTIONS ABOUT YOU

1. At the end of 2006, were you?: (n=141)

52.5%	Single, Widowed, or Divorced
47.5%	Married

2. Which of the following best describes your annual household income for 2006? Please check one box only. (n=139)

19.4%	Less than \$ 15,000
5.8%	\$ 15,000 – \$ 16,999
6.5%	\$ 17,000 – \$ 18,999
3.6%	\$ 19,000 – \$ 20,999
5.0%	\$ 21,000 – \$ 22,999
4.3%	\$ 23,000 – \$ 24,999
42.4%	\$ 25,000 or greater
12.9%	I do not recall.

3. Do you have any of the following chronic conditions? Please respond to each statement. (n=142)

Alzheimer's disease	7.7%	Yes	92.3%	No
Arthritis or joint pain	66.2%	Yes	33.8%	No
Cancer (any kind)	14.8%	Yes	85.2%	No
Diabetes	35.2%	Yes	64.8%	No
High cholesterol	63.4%	Yes	36.6%	No
Hypertension or heart condition	75.4%	Yes	24.6%	No
Kidney disease	7.7%	Yes	92.3%	No
Lung or respiratory condition	19.0%	Yes	81.0%	No
Other, please specify: _____				

4. Have you had any of these other medical conditions in the last two years? Please respond to each statement. (n=142)

Bodily injury	14.8%	Yes	85.2%	No
Eye disorder (glaucoma or cataracts)	35.2%	Yes	64.8%	No
Heart attack	8.5%	Yes	91.5%	No
Infection	24.6%	Yes	75.4%	No
Influenza/flu	14.8%	Yes	85.2%	No
Pneumonia	9.2%	Yes	90.8%	No
Stroke	9.2%	Yes	90.8%	No
Other, please specify: _____				

5. Did you spend at least one night in the hospital or in a nursing home within the last two years because of any of the above conditions? (n=142)

42.3%	Yes
57.7%	No

YOUR EXPERIENCES WITH THE MEDICARE PRESCRIPTION DRUG PROGRAM

6. Did you have prescription drug coverage or assistance before the Medicare Prescription Drug Program? (n=142)

47.2%	Yes
52.8%	No

7. When you enrolled in your Medicare prescription drug plan, did you know that you would face a coverage gap, also known as a donut hole, where you would pay 100% of your prescription costs if your costs reached the initial coverage limit? (n=142)

71.8%	Yes
28.2%	No

8. Did you enter the coverage gap at any point since you enrolled in the Medicare Prescription Drug Program? (n=142)

80.3%	Yes
19.7%	No. If No , go to question #14 on page 6.



**9. How did you know when you would enter the coverage gap?
Please respond to each statement. (n=114)**

I received a special notice from my Prescription Drug Program Plan.	36.0%	Yes	64.0%	No
I determined it from my monthly explanation of benefits.	37.7%	Yes	62.3%	No
My pharmacist told me.	44.7%	Yes	55.3%	No
I kept track of my prescription drug costs.	32.5%	Yes	67.5%	No
I did not know when I would enter the coverage gap.	25.4%			
Other, please specify: _____				

10. Who helped you pay for or obtain your prescription drugs when you entered the coverage gap? Please respond to each statement. (n=114)

The State Pharmacy Assistance Program (SPAP)	4.4%	Yes	95.6%	No
A private pharmaceutical company	3.5%	Yes	96.5%	No
A charitable organization	0.9%	Yes	99.1%	No
A family member or friend	7.9%	Yes	92.1%	No
No one helped me pay for or obtain my prescription drugs when I entered the coverage gap. I paid for them.	80.7%			
Other, please specify: _____				

11. How did you change your prescription drug use after you entered the coverage gap? Please respond to each statement. (n=114)

I switched to a different prescription drug.	18.4%	Yes	81.6%	No
I switched to an over-the-counter drug.	4.4%	Yes	95.6%	No
I used a medication less often than prescribed (for example: I skipped or decreased a dose, or I cut pills).	21.1%	Yes	78.9%	No
I stopped taking 1 or more medications.	15.8%	Yes	84.2%	No
I did not start a new medication.	14.0%	Yes	86.0%	No
I did not change my prescription drug use.	60.5%			
Other, please specify: _____				

12. Before changing your drug use, did you talk to a doctor, nurse, or pharmacist? (n=110)

18.2%	Yes
20.0%	No
61.8%	I did not change my prescription drug use.

13. How did you change the way you purchased or obtained your prescription drugs after you entered the coverage gap? Please respond to each statement. (n=114)

I shopped around and compared prices.	22.8%	Yes	77.2%	No
I switched to a mail-order pharmacy.	11.4%	Yes	88.6%	No
I purchased drugs outside my plan.	7.9%	Yes	92.1%	No
I used free medication samples.	25.4%	Yes	74.6%	No
I used someone else's medication.	0%	Yes	100%	No
I did not change the way I purchased or obtained my prescription drugs.	66.7%			
Other, please specify: _____				

14. If this survey was completed by someone other than the person it was mailed to, please check this box. (n=142)

23.2% Someone else completed this survey.

15. In case we have a question about one of your responses, please list your phone number with area code so we may contact you. Your phone number will be kept confidential.

(____) _____ - _____

**THANK YOU FOR COMPLETING THIS SURVEY.
PLEASE RETURN IT TO US IN THE ENCLOSED ENVELOPE.**

Nonresponse analysis

We analyzed how nonresponse to our survey may have affected our survey estimates. We examined potential nonresponse bias effects on 24 key survey questions. Our nonresponse analysis provided no evidence that our survey results were biased because of nonresponse.

Our basic approach was to impute answers for nonrespondents and determine whether the survey estimate calculated with the imputed values differed significantly from the survey estimate based solely on the respondents' answers. If no statistical difference was found between the two estimates, we considered our survey estimates to be unaffected by potential nonresponse bias.

Variables for both respondent and nonrespondent beneficiaries were age, sex, race, drug benefit type, and plan type. We determined whether respondents and nonrespondents differed based on these variables. They did not differ based on sex, race, and drug benefit type. However, they differed based on plan type and age.

Because nonrespondents were different by plan type and age, we imputed nonrespondents' answers based on the response frequencies of late responders who shared the same plan type and age characteristics. To do this, we classified response time as either "early" or "late" depending on how many attempts it took to obtain a response. Late responders were those who responded to the survey after our third contact attempt. Finally, we conducted statistical tests of significance to determine whether the estimates based on both respondents' answers and nonrespondents' imputed values differed from the estimates based only on respondents' answers.

Estimates and Confidence Intervals

Table D-1: Estimates of Survey Results: Coping Strategies Related to Prescription Drug Purchasing and Use During the Coverage Gap by Beneficiaries Who Reported Entering the Coverage Gap

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Percentage of beneficiaries who reported entering the coverage gap after enrolling in a Part D plan	142	80.3%	73.7%–86.9%
Percentage of beneficiaries who reported seeking less costly alternatives to purchasing drugs (i.e., used a medication less often, stopped taking a medication, or did not start a new medication)	114	37.7%	28.7%–46.8%
Percentage of beneficiaries who reported using free prescription drug samples	114	25.4%	17.3%–33.6%
Percentage of beneficiaries who reported shopping around and comparing prices	114	22.8%	15.0%–30.6%
Percentage of beneficiaries who reported switching to a mail-order pharmacy	114	11.4%	5.5%–17.3%
Percentage of beneficiaries who reported purchasing drugs outside their plan	114	7.9%	2.9%–12.9%
Percentage of beneficiaries who reported receiving at least one type of help in purchasing their prescription drugs	114	14.9%	8.3%–21.6%
Percentage of beneficiaries who reported receiving more than one source of help in purchasing their prescription drugs	114	1.8%	0.2%–6.2%*
Percentage of beneficiaries who reported receiving help from a family member or friend	114	7.9%	2.9%–12.9%
Percentage of beneficiaries who reported receiving help from a State Pharmacy Assistance Program	114	4.4%	0.6%–8.2%
Percentage of beneficiaries who reported receiving help from a private pharmaceutical company	114	3.5%	0.1%–6.9%
Percentage of beneficiaries who reported receiving help from a charitable organization	114	0.9%	0.02%–4.8%*
Percentage of beneficiaries who reported compromising their drug regimens (i.e., used a medication less often, stopped taking a medication, or did not start a new medication)	114	33.3%	24.5%–42.1%
Percentage of beneficiaries who reported using a drug less often than prescribed	114	21.1%	13.5%–28.7%
Percentage of beneficiaries who reported that they stopped taking a medication	114	15.8%	9.0%–22.6%
Percentage of beneficiaries who reported not starting a new medication	114	14.0%	7.6%–20.5%

* Confidence interval calculated with an exact method based on the binomial distribution.

Source: Office of Inspector General (OIG) analysis of beneficiary survey responses, 2008.

Table D-1: Estimates of Survey Results: Coping Strategies Related to Prescription Drug Purchasing and Use During the Coverage Gap by Beneficiaries Who Reported Entering the Coverage Gap, *continued*

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Percentage of beneficiaries who reported not talking to a doctor, nurse, or pharmacist before changing their drug use	110	20.0%	12.4%–27.6%
Percentage of beneficiaries who reported switching to a different prescription drug	114	18.4%	11.2%–25.6%
Percentage of beneficiaries who reported switching to an over-the-counter drug	114	4.4%	0.6%–8.2%

Source: OIG analysis of beneficiary survey responses, 2008.

Table D-2: Estimates of Survey Results: Beneficiaries' Reported Annual Incomes

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Percentage of all beneficiaries who reported that their annual household income was below 150% of the Federal poverty level	176	19.9%	13.9%–25.8%

Source: OIG analysis of beneficiary survey responses, 2008.

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JAN 15 2009

TO: Daniel R. Levinson
Inspector General

FROM: Kerry Weems *Kerry Weems*
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Effect of the Part D Coverage Gap on Beneficiaries without Financial Assistance in 2006" (OEI-05-07-00610)

Thank you for the opportunity to comment on the OIG draft report that examines the experiences of Medicare beneficiaries who exceeded the standard initial coverage limit of \$2,250 in 2006. We are pleased that the findings of the OIG are similar to the findings from the Centers for Medicare & Medicaid Services (CMS) analyses presented at the Medicare Drug Benefit Symposium, held on October 30, 2008 (materials available at: http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/08_PartDDData.asp). The differences between these findings are generally due to slight differences in methodology. Additionally, CMS appreciates the valuable information gained via the survey of beneficiaries' drug purchasing behaviors once they exceeded their initial coverage limit.

In the report, the OIG found that a total of 7.4 million beneficiaries (1.5 million without financial assistance + 5.9 million with financial assistance) had gross drug expenditures that exceeded the standard 2006 initial coverage limit of \$2,250. CMS also found this to be true. However, CMS reported that 30.1 percent of beneficiaries exceeded the standard initial coverage limit of \$2,250, yet the sum of the percents presented by the OIG totals 33 percent (7 percent for those without financial assistance + 26 percent for those with financial assistance). The difference in these reported percentages is due to the difference in the denominators used in the calculations. CMS based its percent on all enrolled beneficiaries in Part D, whereas the OIG based its percent on all utilizing beneficiaries (i.e., excluding those beneficiaries enrolled in Part D who did not utilize the benefit).

The CMS also agrees with the OIG's approach to focus on beneficiaries who did not have any additional financial assistance and reached the initial coverage limit. However, it is important to note that the population studied by the OIG differed from that studied by CMS. The population examined by the OIG analysis was based on utilizing beneficiaries who did not receive any cost sharing assistance after their gross drug expenditures reached \$2,250 (i.e., the amount of the 2006 standard initial coverage limit), according to prescription drug event records. The population evaluated by CMS was based on beneficiaries who exceeded their plan's specific

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initial coverage limit, were not receiving a low-income subsidy according to CMS enrollment records, and were not in a plan that offered extra coverage in the gap according to CMS plan benefit package information. Nonetheless, while the populations evaluated are not directly comparable, the OIG's finding that 7 percent of utilizing beneficiaries reached the standard initial coverage limit and did not have any financial assistance, is generally similar to the finding from CMS that 9.9 percent of beneficiaries who did not have a low-income subsidy and were not in a plan that was listed as offering gap coverage, reached their plan's specific initial coverage limit.

The findings of the OIG for the amount of time spent before the coverage gap and time spent in the coverage gap were also similar to CMS' findings; although CMS' results were based on all beneficiaries including those with financial assistance. Another difference in methodology is that CMS' findings were based on the number of months beneficiaries were actually enrolled in the Part D program, and not only the months in which beneficiaries utilized the benefit.

Additionally, while CMS has yet to completely examine the changes in drug purchasing behavior of beneficiaries after reaching the initial coverage limit, the general findings of the OIG seemed consistent with CMS' preliminary results. These results showed a slight decrease in the average number of monthly prescriptions for beneficiaries who reached their plan's specific initial coverage limit and did not have either low-income subsidy or gap coverage through their plan. However, CMS' analyses also separately examined beneficiaries with a low-income subsidy and found a similar decrease in the average number of monthly prescriptions; yet these beneficiaries did not have a change in cost sharing after reaching the initial coverage limit. This shows the importance of comparison groups, and we believe that the OIG's overall conclusions suffer from the lack of a control group. The current design does not present a true causal analysis of the effect of the gap on drug utilization. Decreased use may be the result of medication fatigue or other trends. Therefore, we cannot be certain the decrease can be attributed to the presence of a coverage gap.

The CMS also appreciates the opportunity to review the information presented by the OIG on the results of the survey of beneficiaries who reached the coverage gap. However, since CMS has not conducted similar survey research, we cannot comment on the generalizability of the findings. CMS does agree with the finding from the survey that pursuing less costly alternatives (such as generic drugs or therapeutic interchanges) is an appropriate drug purchasing approach to reduce the costs for beneficiaries. We would add that switching to less costly alternatives early in the benefit year may also decrease the likelihood of a beneficiary ever reaching his or her initial coverage limit.

Below are CMS' responses to the OIG recommendations provided in this draft report, followed by technical comments.

OIG Recommendation

The CMS should support outreach and education activities targeted at beneficiaries who make more prescription drug purchases before entering the coverage gap.

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CMS Response

The OIG suggests that CMS educate beneficiaries who purchased more drugs during their initial coverage period about cost-saving strategies for purchasing prescription drugs. CMS implements an annual open-enrollment campaign that reaches all beneficiaries. The goal of this campaign is to encourage beneficiaries to review their current plan and to compare among other available plans, so that they can make informed decisions based on costs (e.g., monthly premiums and cost-sharing) and other factors important to beneficiaries (e.g., plan performance or company reputation) when selecting their plan for the next benefit year. These campaigns promote CMS' Medicare Prescription Drug Plan Finder tool, available on Medicare.gov, which estimates the prospective year's costs based on the beneficiary's current drug utilization. In addition, the drug plan finder tool provides information on reducing costs that includes the utilization of therapeutic alternatives and mail-order pharmacy.

The CMS does not believe that it would be useful to provide additional outreach specifically to individual beneficiaries who utilized a large number of drugs per month based on the prior year's prescription drug event data. CMS has improved the Medicare Prescription Drug Plan Finder tool to specifically tailor each user's drug regimen to select cost-saving generic alternatives as the default, and more recently the functionality to further reduce costs by substituting lower-cost therapeutic alternatives. CMS believes that the current outreach provided to all beneficiaries by CMS and the additional outreach provided by Part D sponsors (in general and through their Medication Management Therapy Programs) are effective, and that little more could be done to augment changes in beneficiaries' plan selections or drug purchasing behaviors.

OIG Recommendation

The CMS should target low-income subsidy outreach to beneficiaries who entered the coverage gap without financial assistance.

CMS Response

The CMS concurs with this recommendation and echoes the difficulties also expressed by the OIG in identifying beneficiaries who may be eligible for the subsidy. CMS and its partner organizations continue their outreach efforts to beneficiaries to promote the low-income subsidy LIS and assist eligible beneficiaries. CMS will also continue to utilize messaging that emphasizes the overall value of the LIS in order to target beneficiaries with significant drug utilization who might benefit from the LIS.

Technical Comments

CMS staff provided several verbal comments at the exit conference held on November 18, 2008. These comments do not appear to have been incorporated in the revised draft of the report. These technical comments are as follows:

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- On page 7 of the draft report, the methodology needs to be clarified to state that non-Part D drugs were excluded before tallying gross drug costs.
- As described in the paragraphs above, the methodology utilized by the OIG uses the standard 2006 initial coverage limit of \$2,250; not the initial coverage limit specific to the plan in which each beneficiary was enrolled. This should be described as a limitation of the analysis.
- As described in Appendix A on page 23 of the draft report, calendar months in which a beneficiary utilized the benefit were used instead of enrollment months for monthly cost and utilization calculations. Therefore, these calculations do not represent a typical per member per month (PMPM) metric, commonly used in the insurance industry to represent monthly utilization or expenditures. This should be added as a limitation of the analysis.
 - Also, the “time spent before the coverage gap” may have been longer than reported by the OIG since a beneficiary may have been enrolled prior to having any prescription drug events. Likewise, the “time spent in the coverage gap” may have been shorter than reported by the OIG since a beneficiary may have disenrolled after reaching the coverage gap and prior to the end of the benefit year.
- The denominator for percentages was based on utilizers, not ever-enrolled beneficiaries. While this is not necessarily an error, the report should state that percentages would be lower if including all beneficiaries enrolled in the Part D program during 2006.

Again, we thank you for the opportunity to review and comment on this draft report.



A C K N O W L E D G M E N T S

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Thomas Komaniecki, Deputy Regional Inspector General.

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