Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

MEDICAID REBATES FOR BRAND-NAME DRUGS EXCEEDED PART D REBATES BY A SUBSTANTIAL MARGIN

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Inspector General

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EXECUTIVE SUMMARY: MEDICAID REBATES FOR BRAND-NAME DRUGS EXCEEDED PART D REBATES BY A SUBSTANTIAL MARGIN
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WHY WE DID THIS STUDY

Drug rebates reduce the program costs of both Medicare Part D and Medicaid. Medicaid rebates are defined by statute and include additional rebates when prices for brand-name drugs increase faster than inflation. In contrast, Part D sponsors (or contractors acting on their behalf) negotiate rebates with drug manufacturers, and there are no statutory requirements regarding the amounts of these rebates. A 2011 Office of Inspector General (OIG) report found that statutorily defined Medicaid rebates for selected brand-name drugs exceeded Part D rebates by a substantial margin. The report also found that the inflation-based additional rebate, meant to protect Medicaid from large increases in drug prices, was the primary reason that Medicaid rebates were higher than Part D rebates. A Member of Congress requested an update to the previous OIG report. Specifically, the Member asked OIG to reexamine the prices and rebates under Part D and Medicaid, given the increase in Medicaid rebates under the Affordable Care Act, and to determine the proportion of rebate dollars attributed to inflation-based rebates under Medicaid.

HOW WE DID THIS STUDY

We determined total Part D and Medicaid drug expenditures and rebates in 2012. We also determined total 2012 Part D and Medicaid expenditures and rebates for 200 selected brand-name drugs and compared the differences between the two programs. Further, we determined whether the manufacturers of the selected drugs owed inflation-based rebates and the amount of these inflation-based rebates.

WHAT WE FOUND

Total rebates under Medicaid were substantially higher than total rebates under Medicare Part D. Also, Medicaid's net unit costs (i.e., the pharmacy reimbursement amounts minus rebates) were much lower than net unit costs under Part D in 2012 for the 200 selected brand-name drugs and the statutorily defined Medicaid rebates exceeded Part D rebates by a substantial margin. Further, more than half of Medicaid rebates owed by manufacturers for selected brand-name drugs were attributed to the inflation-based add-on rebates.

WHAT WE CONCLUDE

This is the second OIG evaluation examining the prices and rebates under Medicaid and Medicare Part D. Both evaluations demonstrate the substantial difference in rebates collected under Medicaid and Part D. While we recognize the statutory limitations surrounding rebate collection under Part D, we encourage the Centers for Medicare & Medicaid Services and Congress to explore the costs and benefits of obtaining additional rebates under Part D. Some options include an examination of the impact of "dual eligible" beneficiaries (i.e., beneficiaries eligible for both Medicare and Medicaid) on each program's rebate totals and an analysis of methods to protect Part D from significant increases in drug prices.

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OBJECTIVES

1. To compare the total amount of drug rebates collected by State Medicaid agencies to the total amount of drug rebates collected by Medicare Part D plan sponsors.
2. To compare pharmacy reimbursement amounts (including rebates) under Medicaid to pharmacy reimbursement amounts (including rebates) under Medicare Part D for 200 selected brand-name drugs.
3. To determine the proportion of rebates attributable to inflation-based rebates under Medicaid for 200 selected brand-name drugs.

BACKGROUND

The Patient Protection and Affordable Care Act (ACA)[1] mandated that the Office of Inspector General (OIG) compare the prices (including rebates) for 200 selected drugs under Medicare Part D to the prices (including rebates) for these drugs under Medicaid. In the report that fulfilled this legislative requirement, OIG found that Part D sponsors and State Medicaid agencies paid pharmacies roughly the same amounts for these drugs in 2009; however, statutorily defined Medicaid unit rebate amounts (URAs) for brand-name drugs exceeded Part D URAs by a substantial margin.[2] The report also found that the inflation-based additional rebate was the primary reason that Medicaid rebates were higher than Part D rebates. A Member of Congress requested an update to the previous OIG report. The Member asked OIG to reexamine the prices (including rebates) under Part D and Medicaid, given the increase in Medicaid rebates under the ACA, and to determine the proportion of rebate dollars attributed to inflation-based rebates under Medicaid.

Medicare Part D

The Medicare prescription drug program, known as Medicare Part D, provides an optional prescription drug benefit to all Medicare beneficiaries entitled to Medicare Part A or enrolled in Medicare Part B.[3] The Centers for Medicare & Medicaid Services (CMS) contracts with private companies, known as Part D plan sponsors (hereinafter referred to as sponsors), to provide drug coverage to the beneficiaries who choose to enroll in the program. In 2012, Part D drug expenditures totaled $66.5 billion. Sponsors offer benefits through (1) stand-alone prescription

[1] P.L. No. 111-148.

[2] OIG, *Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D* (OEI-03-10-00320), August 2011.

[3] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173.

drug plans (PDPs) and (2) Medicare Advantage prescription drug plans (MA-PDs). Prior to 2006, low-income senior citizens and disabled individuals who qualified for both Medicare and Medicaid received outpatient drug benefits through Medicaid. When Medicare Part D was implemented in 2006, these "dual eligible" beneficiaries began receiving drug coverage under Medicare.

Medicare Part D Drug Reimbursement and Rebates. Negotiated prices are the basis of pharmacy reimbursement under Part D. They are the amounts the Part D sponsor and pharmacy (or other network dispensing entity) have negotiated as the amount the pharmacy (or other entity) will receive for a particular drug, are reduced by price concessions that the sponsor has elected to pass through to Part D enrollees at the point of sale, and include any dispensing fees.[4] The law establishing the Part D program expressly prohibits the Secretary of Health and Human Services (Secretary) from interfering in the negotiations between the relevant Part D parties or instituting a price structure for the reimbursement of covered Part D drugs.[5] Every time a beneficiary has a prescription filled under Part D, his or her plan sponsor must submit a summary to CMS called the prescription drug event (PDE) record. The PDE record contains drug cost, payment, and utilization data that enable CMS to administer the Part D benefit.

Plan sponsors must also provide CMS with information about rebates from drug manufacturers. Rebates are price concessions that reduce the cost of the program to beneficiaries and the Government. Sponsors are required to report these rebates to CMS in the Direct and Indirect Remuneration (DIR) Reports for Payment Reconciliation (hereafter referred to as DIR Reports).[6] Part D sponsors report DIR data at the plan level and at the national drug code (NDC) level.[7]

Medicaid

The Medicaid program provides medical assistance for certain low-income and medically needy individuals. Medicaid is administered by States and financed using State and Federal funds. Currently, all 50 States and the District of Columbia (States) offer prescription drug coverage as part of

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[4] 42 CFR § 423.100.

[5] See § 1860D-11(i) of the Social Security Act (the Act).

[6] See CMS, *Final Medicare Part D DIR Reporting Requirements for 2012*, June 7, 2013, p. 1. See also § 1860D-15(f)(1)(A) of the Act.

[7] See CMS, *Final Medicare Part D DIR Reporting Requirements for 2012*, June 7, 2013, pp. 12 and 20. An NDC is an 11-digit identifier that represents a specific manufacturer, product, and package size.

their Medicaid benefit packages. OIG estimates that Medicaid drug expenditures were approximately $35.7 billion in 2012.[8]

Medicaid Drug Reimbursement and Rebates. State Medicaid agencies reimburse pharmacies for drugs dispensed to Medicaid beneficiaries. CMS and the States have implemented the Medicaid drug rebate program to reduce expenditures for Medicaid covered outpatient drugs. Drug manufacturers are generally required to enter into rebate agreements with the Secretary and pay quarterly rebates to States for Federal payment to be available for covered outpatient drugs provided under Medicaid.[9] As of December 2014, all States and approximately 600 pharmaceutical companies participated in the Medicaid drug rebate program.[10] States invoice manufacturers for the units reimbursed and manufacturers then pay the rebates to the States.

As of 2010, the ACA increased URAs for brand-name and generic drugs. The basic URA for brand-name drugs is either 23.1 percent of AMP or the difference between AMP and best price, whichever is greater.[11] Manufacturers are required to pay an additional rebate amount if the AMP for a brand-name drug has risen faster than inflation.[12] The URA for generic drugs is equal to 13 percent of AMP.[13]

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[8] This estimate was calculated from two sources: CMS's Medicaid Budget and Expenditure System (MBES) and Medicaid State utilization data. To calculate this estimate, we combined the fee-for-service Medicaid expenditures from MBES and the expenditures from Managed Care Organization (MCO) records in the Medicaid State utilization data. This total does not include rebates and excludes problematic MCO utilization data from one State.

[9] Sections 1927(a)(1) and (b)(1) of the Act.

[10] Under this program, manufacturers must provide CMS with average manufacturer prices (AMPs) for their covered outpatient drugs. The AMP is the average price paid to a manufacturer of a drug in the United States by a wholesaler for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer, with certain exclusions. See §§ 1927(b)(3) and 1927(k)(1) of the Act.

[11] Section 1927(c)(1) of the Act as amended by § 2501(a) of the ACA. The minimum rebate percentage for certain brand-name drugs (e.g., a clotting factor for which a separate furnishing payment is made or a drug approved exclusively for pediatric indications) is 17.1 percent of AMP. "Best price" is defined in § 1927(c)(1)(C)(i) of the Act as essentially the lowest price available from the manufacturer during the rebate period to any purchaser in the United States, with certain exceptions.

[12] Section 1927(c)(2) of the Act. The ACA also set a maximum rebate amount for brand-name drugs at 100 percent of AMP. See § 1927(c)(2)(D) of the Act.

[13] Section 1927(c)(3) of the Act as amended by § 2501(b) of the ACA.

METHODOLOGY

Data Collection and Analysis

Data Collection. We obtained from CMS the Part D PDE records—which contain Part D payment and utilization data for all covered drugs provided through PDPs and MA-PDs—with dates of service in 2012. Using payment data from the PDE records and drug-type information from two national drug compendia[14] and Medicaid drug product data, we selected the 200 brand-name drugs (i.e., NDCs) with the highest Part D expenditures in 2012. We limited our analysis to brand-name drugs because our analysis indicated that brand-name drugs account for the majority of expenditures under Medicare Part D and Medicaid. We obtained total 2012 Part D drug expenditures from the 2013 Medicare Trustees' Report[15] and total 2012 Part D rebates from DIR data in CMS's Health Plan Management System. We downloaded total 2012 Medicaid drug expenditures from MBES and CMS's Web site, downloaded total 2012 rebates from MBES, and obtained quarterly URAs from CMS.

Data Analysis. We determined total Part D and Medicaid expenditures and rebates for all drugs in 2012. We also determined total 2012 Part D and Medicaid expenditures and rebates for 200 selected brand-name drugs. For each of the 200 selected brand-name drugs in each program, we calculated the (1) average unit reimbursement amount, (2) average URA, and (3) average net cost (i.e., average unit reimbursement amount minus the average URA) and compared the differences between the two programs. Further, we determined whether the manufacturers of the selected drugs owed inflation-based rebates under Medicaid and, if so, the amount of the inflation-based rebates.[16]

Limitations

The findings in this report related to the selected drugs apply only to those drugs and are not projectable to other drugs. We did not verify the accuracy or completeness of data from the drug compendia or of Medicare or Medicaid data from CMS. The prices that serve as the bases for Medicaid rebate data are subject to revision. The Medicaid rebates we calculated are rebates owed by manufacturers and not necessarily the amounts collected by the States; the rebates reported under Part D represent rebates paid as well as rebates that are expected for the

[14] The compendia were *First Databank* and *Red Book*.

[15] *2013 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*.

[16] To do this, we calculated the quarterly base rebate amount for each brand-name drug and subtracted it from the drug's quarterly URA.

applicable year. We did not include supplemental Medicaid rebates[17] or nonrebate DIR totals in the analysis.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

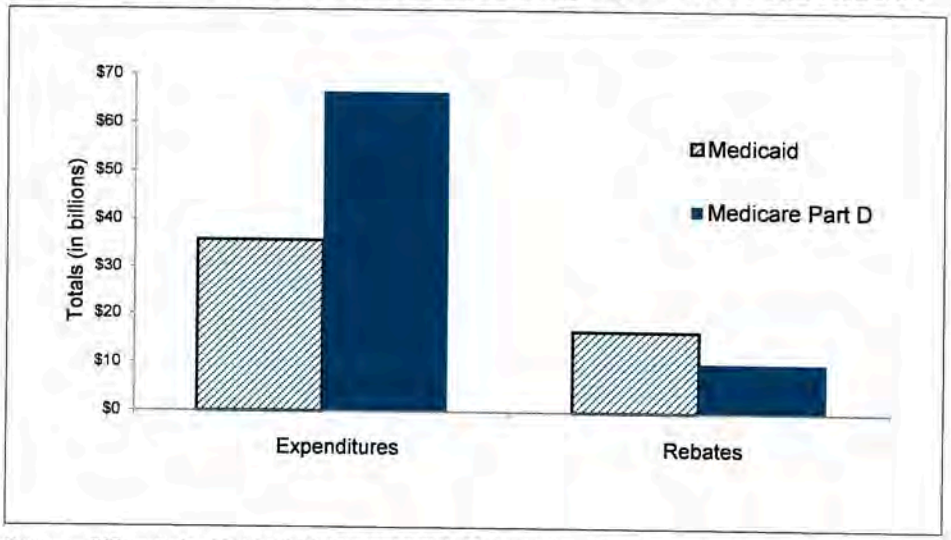
[17] Therefore, this analysis provides a low estimate of total rebates available through Medicaid.

FINDINGS

Total drug rebates under Medicaid were substantially higher than total rebates under Medicare Part D in 2012

Although Medicaid drug expenditures were much lower than Medicare Part D expenditures in 2012 ($35.7 billion vs. $66.5 billion), Medicaid rebates substantially exceeded Part D rebates ($16.7 billion vs. $10.3 billion). As a result, rebates were a substantially higher percentage of expenditures in the Medicaid program. In 2012, rebates accounted for 47 percent of Medicaid expenditures, whereas rebates totaled 15 percent of Part D expenditures. See Figure 1 for a comparison of expenditures and rebates under Medicaid and Part D.

Figure 1. Medicaid and Medicare Part D Drug Expenditures and Rebates



Sources: OIG analysis of 2012 MBES data, 2012 State Medicaid utilization and rebate data, the *2013 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, and 2012 Part D DIR reports.

Pharmacy reimbursement was similar under Medicare Part D and Medicaid; however, after accounting for rebates, Medicaid net costs for selected brand-name drugs were much lower than Part D net costs

Although average Part D and Medicaid reimbursement amounts for most of the 200 selected brand-name drugs under review were similar, Medicaid unit rebates for these drugs were substantially higher than those under Part D. Additionally, Medicaid's net unit costs (i.e., pharmacy reimbursement minus rebates) were much lower than net unit costs under

Part D.[18] The difference between the average Part D and Medicaid unit reimbursement amounts for over two-thirds (135 of 200) of the 200 selected brand-name drugs was less than 2 percent. Average pharmacy reimbursement differed by more than 2 percent and less than 5 percent for an additional 46 of the selected drugs.

However, Medicaid URAs for selected brand-name drugs were substantially higher than Part D URAs

Overall, Medicaid URAs were three times higher than Part D unit rebate amounts at the median for the selected brand-name drugs under review.[19] For 138 drugs, manufacturers owed at least twice as much per unit in Medicaid rebates in 2012 compared to amounts paid per unit under Part D. For 37 of these drugs, Medicaid URAs were over 10 times higher than Part D URAs. Conversely, Part D URAs exceeded Medicaid URAs for just two of the selected brand-name drugs under review. See Table 1 for additional information on rebates under Part D and Medicaid.

Table 1. Comparison of URAs Under Medicaid and Part D for Selected Brand-Name Drugs

Difference in URA*	Number of Drugs
Medicaid more than 10 times higher than Part D	37
Medicaid 6 to 10 times higher than Part D	21
Medicaid 3 to 6 times higher than Part D	35
Medicaid 2 to 3 times higher than Part D	45
Medicaid up to 2 times higher than Part D	42
Medicaid lower than Part D	2
Total number of drugs	**182****

Source: OIG analysis of 2012 Medicaid utilization and Part D PDE data.
*Each range does not include the lower endpoint.
**See footnote 19.

Medicaid net costs for selected brand-name drugs were much lower than Part D net costs

Medicaid's net unit costs for selected brand-name drugs (i.e., pharmacy reimbursement minus rebates) were much lower at the median than net unit costs under Part D in 2012. In fact, after accounting for rebates, Medicaid net unit costs were less than half of Part D net unit costs for 110 brand-name drugs. Medicaid net unit costs exceeded Part D net unit costs for only five brand-name drugs.

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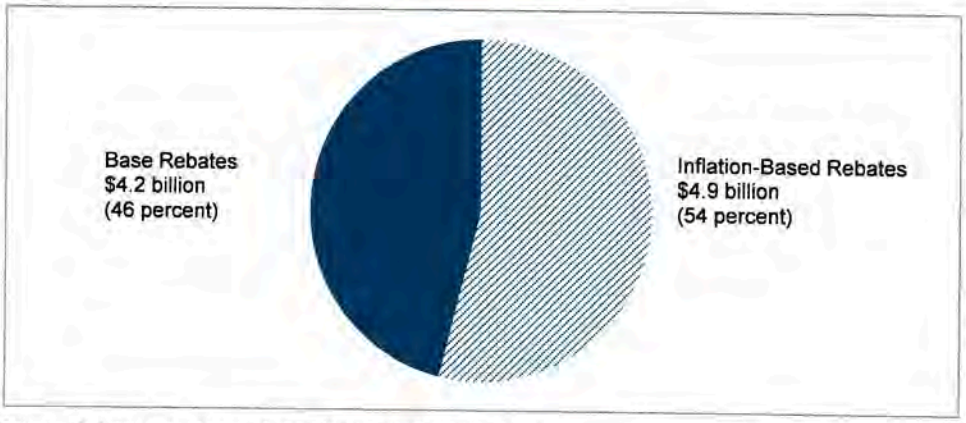
[18] This is generally similar to the results of our previous work that compared reimbursement and rebates from 2009. See OIG, *Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D* (OEI-03-10-00320), August 2011.

[19] We excluded 18 drugs from this portion of the analysis because their Part D rebates totaled less than 0.1 percent of expenditures.

More than half of Medicaid rebates owed by manufacturers for selected brand-name drugs were attributed to the inflation-based add-on rebates

In 2012, the basic URA for a brand-name drug was generally the greater of 23.1 percent of the AMP or the difference between the AMP and best price. If the AMP for a brand-name drug rose faster than inflation, then the drug's manufacturer owed an additional rebate over and above the basic rebate. According to our calculations, manufacturers owed this additional rebate in at least one quarter of 2012 for 191 of the selected 200 brand-name drugs under review. In the aggregate, 54 percent of the total Medicaid rebates owed by manufacturers for the 200 selected brand-name drugs under review ($4.9 billion out of $9.1 billion) can be attributed to AMPs' rising faster than inflation (see Figure 2).

Figure 2. Inflation-Based Rebates as a Percentage of Total Rebates for Selected Drugs



Source: OIG analysis of 2012 Medicaid rebate and utilization data.

The base Medicaid URA by itself exceeded the Part D URA for most selected drugs

The base Medicaid URA by itself exceeded the Part D URA for 141 of the selected brand-name drugs.[20] The addition of the inflation-based rebate further magnified the difference. The add-on URA alone exceeded the Part D URA for 120 selected brand-name drugs and was at least double the Part D URAs for 72 of these drugs.

[20] We excluded 26 NDCs from this portion of the analysis because the Part D rebates totaled less than 0.1 percent of Part D expenditures and/or the drug was not associated with Medicaid add-on rebates.

CONCLUSION

Drug rebates reduce the program costs of both Medicare Part D and Medicaid. Medicaid rebates are defined by statute and include additional rebates when prices for brand-name drugs increase faster than inflation. In contrast, Part D sponsors (or contractors acting on their behalf) negotiate rebates with drug manufacturers, and there are no statutory requirements regarding the amounts of these rebates. In fact, the law establishing the Part D program expressly prohibits the Government from instituting a price structure for the reimbursement of covered Part D drugs.

We found that Part D sponsors and State Medicaid agencies paid pharmacies similar amounts for most brand-name drugs under review. However, Medicaid rebates for brand-name drugs exceeded Part D rebates by a substantial margin. Additionally, Medicaid's net unit costs (i.e., pharmacy reimbursement minus rebates) were much lower than net unit costs under Part D in 2012 for nearly all selected drugs. Also, more than half of Medicaid rebates owed by manufacturers for selected brand-name drugs were attributed to the inflation-based add-on rebates.

A major driver of the higher Medicaid rebates was the additional amount owed when prices for brand-name drugs increase faster than inflation. This rebate not only produces additional Medicaid rebates, but also helps protect the program from increased costs when manufacturers raise prices. The Part D program does not contain a similar provision.

This is the second OIG evaluation that demonstrates the substantial difference in rebates collected under Medicaid and Medicare Part D. While we recognize the statutory limitations surrounding rebate collection under Part D, we encourage CMS and Congress to explore the costs and benefits of obtaining additional rebates under Part D. Some options include an examination of the impact of dual-eligible beneficiaries on each program's rebate totals and an analysis of methods to protect Part D from increases in drug prices.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS responded that section 1860D-11(i)(1) of the Act states that CMS "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors." CMS stated that consequently, it cannot interfere—absent new legislative authority—in the rebate negotiations between Part D sponsors and drug manufacturers to secure additional rebates. OIG recognizes the statutory limitations surrounding rebate collection under Part D and continues to encourage CMS and Congress to explore the costs and benefits of obtaining additional rebates under Part D.

We did not make any changes to the report on the basis of CMS's comments. For the full text of CMS's comments, see the Appendix.

APPENDIX

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

NOV 24 2014

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: "Update: Higher Drug Rebates Result in Lower Costs for Medicaid Compared to Medicare Part D" (OEI-03-13-00650)

The Centers for Medicare and Medicaid Services appreciates the opportunity to review and comment on the OIG's draft report. The Part D program has significantly outperformed cost estimates, resulting in lower than expected premium levels since the inception of the program. Additionally, starting in 2011, brand drug manufacturers provide a 50 percent discount for their products to beneficiaries in the Part D coverage gap phase of the benefit.

As this report discussed, minimum drug manufacturer rebates under the Medicaid program are defined by statute whereas similar rebates under the Medicare Part D program are determined solely through negotiations between drug manufacturers and Part D sponsors. However, Section 1860D-11(i)(1) of the Social Security Act states that CMS "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors." Consequently, absent new legislative authority, CMS cannot interfere in the rebate negotiations between Part D sponsors and drug manufacturers to secure additional rebates.

The Part D program has significantly outperformed cost estimates, resulting in lower than expected premium levels since the inception of the program. Additionally, starting in 2011, brand drug manufacturers provide a 50 percent discount for their products to beneficiaries in the Part D coverage gap phase of the benefit.

Thank you for the opportunity to review and comment on this draft OIG report.

ACKNOWLEDGMENTS

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Edward K. Burley served as the team leader for this study. Other Office of Evaluation and Inspections staff from the Philadelphia regional office who conducted the study include Stefanie Vance. Central office staff who provided support include Eddie Baker, Meghan Kearns, and Christine Moritz.