Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

HIGHER REBATES FOR BRAND-NAME DRUGS RESULT IN LOWER COSTS FOR MEDICAID COMPARED TO MEDICARE PART D

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EXECUTIVE SUMMARY

OBJECTIVES

1. To compare pharmacy reimbursement under Medicare Part D to pharmacy reimbursement under Medicaid for selected drugs.
2. To compare manufacturer rebates under Medicare Part D to manufacturer rebates under Medicaid for selected drugs.
3. To compare net drug costs under both programs and determine the effect that differences may have on overall program costs.

BACKGROUND

Section 3313(b) of the Affordable Care Act (ACA), P.L. 111-148, directs the Office of Inspector General to complete a study by October 1, 2011, that (1) compares the prices paid (including rebates) for 200 covered Part D drugs by Part D plan sponsors to the prices paid (including rebates) for the same drugs by State plans under Medicaid and (2) assesses the impact of price differences.

Medicare Part D provides an optional prescription drug benefit to all Medicare beneficiaries. The Centers for Medicare & Medicaid Services (CMS) contracts with private companies (hereinafter referred to as sponsors) to provide drug coverage to beneficiaries who choose to enroll in the program. The Part D program relies on sponsors to negotiate drug manufacturer rebates to reduce the cost of the program to beneficiaries and the Government. Because rebates are subtracted from the sponsor's costs, they lower the beneficiary's premium and the cost to the Government.

The Medicaid drug rebate program was established to reduce expenditures for Medicaid prescription drugs. For Federal payment to be available for covered outpatient drugs under Medicaid, the Social Security Act mandates that drug manufacturers enter into rebate agreements with the Secretary of Health & Human Services, report quarterly average manufacturer prices (AMP) to CMS for each of their covered outpatient drugs, and pay quarterly rebates to State Medicaid agencies. The Medicaid rebate amount for any given drug generally depends on the quarterly AMP. In addition, if the AMP for a brand-name drug has risen faster than inflation, then the manufacturer must pay an additional rebate.

In 2005, Medicaid paid in excess of $43 billion for prescription drugs; however, drug expenditures decreased by almost half in the following

year, when drug coverage for dual eligible beneficiaries (i.e., beneficiaries eligible for both Medicare and Medicaid) shifted from Medicaid to Medicare Part D. Medicaid expenditures for prescription drugs totaled just under $26 billion in 2009. In the last year before coverage for dual eligibles was moved to Part D (2005), Medicaid rebates totaled about 26 percent of drug expenditures. However, although Medicaid expenditures decreased by almost half after 2005, Medicaid rebates as a percentage of expenditures increased. As a result of these rebates, Medicaid recouped between 29 and 38 percent of its expenditures for prescription drugs each year between 2006 and 2009, yielding an average annual savings of about $8 billion.

For this review, we compared pharmacy reimbursement and rebates under Medicare Part D and Medicaid for the 100 brand-name and 100 generic drugs with the highest Part D expenditures. We then examined each program's net costs and determined the effect of differences on overall costs.

FINDINGS

In 2009, pharmacy reimbursement amounts under Medicare Part D and Medicaid were similar for most selected brand-name drugs but differed substantially for over half of selected generic drugs. For 70 of the 100 brand-name drugs under review, the difference between the average Part D and Medicaid unit reimbursement amounts was less than 2 percent. For more than half (53) of the generic drugs under review, pharmacy reimbursement under Part D and Medicaid differed by more than 15 percent.

For all 30 brand-name drugs for which the reimbursement difference exceeded 2 percent, it was Medicaid that paid more. Overall, Medicaid reimbursement was higher for 63 brand-name drugs; Part D reimbursement was higher for the remaining 37.

In 2009, Medicaid unit rebate amounts for brand-name drugs were substantially higher than Part D unit rebate amounts; rebates for generic drugs under both programs were negligible. Overall, Medicaid unit rebate amounts were 3 times greater than Part D unit rebate amounts at the median for the 100 brand-name drugs under review. For 68 of these drugs, manufacturers paid at least twice as much per unit in Medicaid rebates compared to amounts paid per unit under Part D. Conversely, Part D unit rebate amounts exceeded

Medicaid unit rebate amounts for just five of the brand-name drugs under review.

Unlike rebates for brand-name drugs, rebates for generic drugs had little impact in reducing expenditures. Part D sponsors collected virtually no Part D rebates for generic drugs, and Medicaid rebates for generic drugs reduced total expenditures by only 3 percent.

Medicaid rebates were substantially higher than Part D rebates because manufacturers for virtually all brand-name drugs under review paid inflation-based rebates in addition to basic rebates. For 98 of the 100 brand-name drugs under review, manufacturers paid this additional rebate in all 4 quarters of 2009. In the aggregate, 55 percent of the total Medicaid rebates owed by manufacturers for the 100 brand-name drugs under review ($1.6 billion out of $2.9 billion) are owed because AMPs rose faster than inflation.

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 brand-name drugs under review were similar, Medicaid unit rebates for these drugs were substantially higher than those under Part D. Consequently, Medicaid's net unit costs (i.e., pharmacy reimbursement minus rebates) were much lower than net unit costs under Part D in 2009.

As previously stated, Medicaid unit reimbursement amounts were actually higher than Part D unit reimbursement amounts for 63 brand-name drugs. However, after accounting for rebates, Medicaid net unit costs were higher than Part D net unit costs for only 7 drugs; Part D net unit costs exceeded Medicaid unit costs for the remaining 93.

As further evidence of Medicaid's substantially higher unit rebate amounts, Medicaid collected nearly two-thirds as much in rebates as Part D ($2.9 billion vs. $4.5 billion) for the selected drugs despite having only about one-fourth of the expenditures ($6.4 billion vs. $24 billion). In 2009, rebates reduced Part D expenditures by 19 percent for the 100 brand-name drugs under review (from $24 billion to $19.5 billion). Medicaid rebates accounted for a substantially higher percentage of total expenditures, reducing expenditures by 45 percent (from $6.4 billion to $3.5 billion) for these 100 drugs.

CONCLUSION

Prescription drug rebates reduce the program costs of both Medicare Part D and Medicaid. Medicaid rebates are defined by statute; additional rebates are required when prices for brand-name drugs increase faster than inflation. Unlike the Medicaid program, Part D sponsors (or contractors acting on their behalf) negotiate rebates with drug manufacturers without any statutory requirements on rebate amounts. 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.

In this review, we found that Part D sponsors and State Medicaid agencies paid pharmacies similar amounts for most brand-name drugs under review. However, statutorily defined Medicaid unit rebate amounts for brand-name drugs exceeded Part D unit rebate amounts by a substantial margin. As a result, Medicaid collected nearly two-thirds as much as Part D in rebates for the 100 brand-name drugs ($2.9 billion vs. $4.5 billion), despite having only about one-fourth of the expenditure ($6.4 billion vs. $24 billion).

Medicaid rebates for brand-name drugs may increase as a result of ACA provisions that raise the rebate percentage. Given the potential impact on beneficiary and Government expenditures, we believe that it is important for CMS to continually examine any differences in how each program collects rebates.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS agreed with our overall findings. CMS stated that it was pleased OIG confirmed that the Medicaid rebate program is working well and providing substantial rebates to offset the high costs of prescription drugs. CMS agreed that the ACA may further increase Medicaid rebates for brand-name drugs and that it is important to continue to examine the differences in how each program collects rebates. We did not make any changes to the report based on CMS's comments.

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Medicare Part D Drug Coverage

The Medicare prescription drug program, known as Medicare Part D, provides an optional prescription drug benefit to all Medicare beneficiaries.[1] 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 nearly 30 million beneficiaries who choose to enroll in the program.[2] Part D expenditures totaled $61 billion in 2009.[3]

Sponsors offer benefits through (1) stand-alone prescription drug plans (PDP) and (2) Medicare Advantage prescription drug plans (MA-PD). MA-PDs provide integrated medical coverage, including drugs, through managed care. Most beneficiaries are responsible for certain costs, which may include a monthly premium, an annual deductible, and

[1] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173.

[2] CMS, *2010 Enrollment Information.* Accessed at http://www.cms.hhs.gov on March 11, 2011.

[3] The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2010 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, p. 10. Accessed at http://www.cms.gov on October 13, 2010.

coinsurance or copayments. However, certain low-income beneficiaries are eligible to receive assistance to pay some or all of these costs.[4]

Dual eligibles. When Medicare Part D was implemented in 2006, more than 6 million low-income senior citizens and disabled individuals were full-benefit dual eligibles, i.e., beneficiaries enrolled in both Medicare and Medicaid. Until December 31, 2005, dual eligibles received outpatient drug benefits through Medicaid. However, on January 1, 2006, Federal financial participation ended for Medicaid drug coverage for dual eligibles.[5] Instead, dual eligibles now receive drug coverage under Part D.

Medicare Part D Drug Reimbursement

Beneficiaries enrolled in Medicare Part D typically obtain drugs from pharmacies. Pharmacy reimbursement (i.e., the point-of-sale price) under Part D is based on prices negotiated between pharmacies and sponsors (hereinafter referred to as negotiated prices). Regulation defines negotiated prices as prices for covered Part D drugs that: (1) the sponsor (or its affiliated contractor) and pharmacy have negotiated as the amount the pharmacy will receive for a particular drug, (2) are reduced by price concessions[6] that the sponsor has elected to pass through to Part D enrollees at the point of sale, and (3) include any pharmacy dispensing fees.[7] Negotiated prices contain two main elements:[8]

1. Ingredient cost – the amount paid to the pharmacy for the drug itself.
2. Dispensing fee – the amount paid to the pharmacy for dispensing the drug. This amount includes only those activities related to the transfer of the drug from the pharmacy to the beneficiary, including charges associated with mixing the drug, delivery, and overhead.[9]

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[4] 42 CFR § 423.780 and 42 CFR § 423.782.

[5] Section 1935 of the Social Security Act (the Act).

[6] Rebates from drug manufacturers are the most common type of price concession.

[7] 42 CFR § 423.100.

[8] Negotiated prices for Medicare Part D also include a data element for sales tax. See CMS, *Instructions: Requirements for Submitting Prescription Drug Event Data.* Accessed at http://www.cms.hhs.gov on October 4, 2010.

[9] CMS, *Instructions: Requirements for Submitting Prescription Drug Event Data.* Accessed at http://www.cms.hhs.gov on October 4, 2010.

The ingredient cost of the drug is usually based on the lowest of (1) the average wholesale price (AWP) discounted by a specified percentage,[10] (2) the maximum allowable cost, or (3) the pharmacy's usual and customary charge to the public.[11] The portion of the negotiated price paid by the plan sponsor and the portion paid by the beneficiary are determined by the plan's cost-sharing rules. Reimbursement is negotiated among sponsors, manufacturers, and pharmacies; the law creating the Part D program expressly prohibits the Government from establishing a price structure for the reimbursement of drugs under Part D.[12]

All sponsors submit data and information necessary for CMS to determine and make payment.[13] Every time a beneficiary has a prescription filled under Part D, his or her plan must submit a prescription drug event (PDE) record. The PDE record contains drug cost, payment, and utilization data.[14]

Medicare Part D Rebates

Sponsors negotiate drug manufacturer rebates to reduce the cost of the Part D program to beneficiaries and the Government. Sponsors either negotiate directly with manufacturers for rebates or contract with a third party entity to negotiate on their behalf; in either case they are required to report these rebates to CMS.

Before the beginning of each year, sponsors submit a bid to CMS for each plan they intend to offer.[15] The bids are the sponsors' estimates of the cost to provide the prescription drug benefit to each beneficiary and include drug costs, utilization, and rebates. In its bid instructions, CMS

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[10] AWPs are listed in commercial publications. They are derived from manufacturer-reported data for both brand-name and generic drugs and are not defined in law or regulation. Previous OIG work found that AWPs are often significantly higher than the prices that drug manufacturers, wholesalers, and similar entities actually charge the physicians and pharmacies that purchase these drugs. For example, see OIG, *Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products* (A-06-00-00023), August 2001; *Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products* (A-06-01-00053), March 2002; and *Medicaid's Use of Revised Average Wholesale Prices* (OEI-03-01-00010), September 2001.

[11] If ingredient cost is based on the usual and customary charge, the pharmacy is not paid a dispensing fee.

[12] Section 1860D-11(i) of the Act.

[13] Sections 1860D-15(c)(1)(C) and (d)(2) of the Act, 42 CFR § 423.322.

[14] CMS, *Instructions: Requirements for Submitting Prescription Drug Event Data*. Accessed at http://www.cms.hhs.gov on October 4, 2010.

[15] 42 CFR § 423.265.

defines expected rebates as the sponsor's best estimate of price concessions that decrease the sponsor's costs for Part D drugs.[16] CMS uses the bids to calculate each plan's beneficiary premium. Because expected rebates are subtracted from the sponsor's expected costs, they lower the bid amount and, thus, the beneficiary's premium.

CMS, using these bids, makes prospective payments to sponsors to cover the cost of providing the Part D benefit. Therefore, the overall cost of the program to the Government is reduced because expected rebates are subtracted from expected costs. In an annual rebate report after the end of the year, sponsors must provide CMS with information about the actual costs, including the amount of rebates that they received.[17] CMS uses these reports to reconcile its prospective payments with sponsors' actual costs and thus, to determine whether sponsors owe money to the Government or vice versa.

Medicaid Drug Coverage

Title XIX of the Act established Medicaid, a program administered by States and financed with State and Federal funds. Medicaid pays for medical care and health-related assistance for certain vulnerable and needy individuals and families. All 50 States and the District of Columbia provide coverage for drugs under Medicaid. In 2005, Medicaid paid in excess of $43 billion for prescription drugs; however, drug expenditures decreased by almost half in the following year, when drug coverage for dual eligible beneficiaries shifted from Medicaid to Part D. Since 2006, Medicaid payments for prescription drugs have remained relatively steady (see Table 1 on page 6). In 2009, Medicaid expenditures for drugs totaled approximately $26 billion.

Medicaid Drug Reimbursement

Medicaid beneficiaries typically receive covered drugs through pharmacies, which are reimbursed for them by State Medicaid agencies. Federal regulations require, with certain exceptions, that each State Medicaid agency's reimbursement for covered outpatient drugs not exceed (in the aggregate) the lower of the provider's usual and customary charge to the public for the drugs or the estimated

[16] CMS, *Instructions for Completing the Prescription Drug Plan Bid Pricing Tool for Contract Year 2011*, April 2010.

[17] CMS, *Medicare Part D Reporting Requirements*, January 2010.

acquisition cost for drugs (i.e., the ingredient cost) plus a reasonable dispensing fee.[18] These costs are defined as:

1. Ingredient cost. Medicaid payment for ingredient cost is based on the estimated acquisition cost. Regulations define estimated acquisition cost to be the State's "best estimate" of the price generally and currently paid by providers for the drug.[19] CMS allows States flexibility in determining what constitutes the ingredient cost of drugs covered by their Medicaid programs; therefore, Medicaid reimbursement varies across States. During the period covered by this review (i.e., 2009), most States calculated the estimated acquisition cost based on the AWP discounted by a specified percentage.[20] For certain drugs, States also used the Federal upper limit or State maximum allowable cost programs in setting reimbursement amounts.[21, 22]

2. Dispensing fee. State Medicaid agencies also pay a "reasonable" dispensing fee to pharmacies for pharmacy services. Each State determines its Medicaid dispensing fee, which generally ranged from $1.75 and $7.50 per prescription as of December 2009.[23]

The Medicaid Drug Rebate Program

To reduce expenditures for Medicaid prescription drugs, CMS and the States have implemented certain cost containment measures, including the Medicaid drug rebate program. For Federal payment to be available for covered outpatient drugs under Medicaid, the Act mandates that drug manufacturers enter into rebate agreements with the Secretary of

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[18] 42 CFR § 447.512.
[19] 42 CFR § 447.502.

[20] CMS, *Medicaid Prescription Reimbursement Information by State – Quarter Ending December 2009*. Accessed at http://www.cms.hhs.gov on March 9, 2011.

[21] The Federal upper limit program limits Medicaid reimbursement for certain generic drugs and ensures that the Federal Government acts as a prudent buyer by taking advantage of current market prices for generic drugs.

[22] A maximum allowable cost is a ceiling price that applies to a group of generic drugs. Individual States determine which drugs are included in their programs and the methods by which the maximum allowable cost for a drug is calculated.

[23] CMS, *Medicaid Prescription Reimbursement Information by State – Quarter Ending December 2009*. Accessed at http://www.cms.hhs.gov on March 9, 2011. This range excludes drugs dispensed through nonretail pharmacies, compounded drugs, and home intravenous therapy.

Health & Human Services and pay quarterly rebates to State Medicaid agencies.[24]

In the last year before coverage for dual eligibles was moved to Part D (2005), Medicaid collected $11.2 billion in rebates from manufacturers (26 percent of total drug expenditures). However, as Table 1 illustrates, although Medicaid expenditures decreased by almost half after 2005, Medicaid rebates as a percentage of expenditures increased. As a result of these rebates, Medicaid recouped between 29 and 38 percent of its expenditures for prescription drugs each year between 2006 and 2009, yielding an average annual savings of about $8 billion.[25, 26] See Table 1 for additional information on Medicaid expenditures and rebates.

Table 1: Medicaid Expenditures and Rebates 2005–2009

Year	Expenditures	Medicaid Rebates	Rebates as a Percentage of Expenditures
2005	$43.2 billion	$11.2 billion	26%
2006	$22.5 billion	$8.6 billion	38%
2007	$22.6 billion	$6.6 billion	29%
2008	$24.0 billion	$8.0 billion	33%
2009	$25.6 billion	$9.0 billion	35%

Source: CMS Medicaid data for calendar years 2005–2009.

As part of the Medicaid drug rebate program, manufacturers must provide CMS with the average manufacturer price (AMP) for each of their national drug codes (NDC) on a quarterly basis.[27] An NDC is a unique 11-digit identifier that represents a specific manufacturer, product, and package size. During the period covered by this review, the AMP was generally defined as the average price paid to the

[24] Sections 1927(a)(1) and (b)(1) of the Act. Sections 1927(k)(2–3) of the Act define a covered outpatient drug.

[25] According to CMS staff, the substantial increase in rebates as a percentage of expenditures from 2005 to 2006 may be partially explained by the time lag between when expenditures occur and when the rebates are actually collected.

[26] States can negotiate supplemental rebates with drug manufacturers that are in addition to the statutory rebates in Table 1. From 2005 to 2009, State Medicaid agencies collected approximately $1 billion per year in supplemental rebates that would further reduce Medicaid expenditures.

[27] Section 1927(b)(3) of the Act.

manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.[28]

The Medicaid unit rebate amount (URA) for a drug generally depends on the quarterly AMP submitted by the manufacturer, as well as whether the drug is brand-name or generic (because the Medicaid rebate for brand-name drugs is higher).[29] From 1996 to 2009, the basic URA for a brand-name drug was either 15.1 percent of the AMP or the difference between the AMP and best price (whichever was greater).[30, 31] The basic URA for a generic drug was 11 percent of the AMP.

Furthermore, if the AMP for a brand-name drug has risen faster than inflation, then the drug's manufacturer must pay an additional rebate.[32] To determine whether a brand-name drug is subject to the increased rebate amount, CMS compares the reported AMP for a given quarter to its inflation-adjusted baseline AMP. The baseline AMP for a drug is the AMP for the first quarter after the drug's initial market date. To adjust the baseline AMP for inflation, CMS first divides the baseline AMP by the baseline Consumer Price Index–Urban (CPI-U), which is the CPI-U for the first month prior to the first quarter after the drug's initial market date. The result of that calculation is then multiplied by the quarterly CPI-U, which is the CPI-U for the month prior to the quarter being calculated. If the reported AMP is greater than the inflation-adjusted baseline AMP, then the difference is added to the URA.

CMS calculates a URA for each NDC and transmits that information to States. States then determine the total quarterly rebates that

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[28] Section 1927(k)(1) of the Act. Section 2503 of the ACA changed the definition of AMP, effective October 2010. That change is not relevant for the purposes of this study.

[29] Brand-name drugs are approved by the Food and Drug Administration (FDA) under a new drug application and are generally sold by one manufacturer. Generic drugs are approved by FDA under abbreviated new drug applications and are generally sold by multiple manufacturers at a lower cost.

[30] Section 1927(c) of the Act. Pursuant to section 1927(b)(3)(A)(i)(II) of the Act, manufacturers must provide a "best price" for each of their brand-name drugs on a quarterly basis. Generally speaking, best price is defined by section 1927(c)(1)(C) of the Act as the lowest price available from the manufacturer to any purchaser in the United States, with certain exceptions.

[31] Effective January 2010, § 2501(a) of the ACA increases the URA for brand-name drugs to the greater of 23.1 percent of the AMP or the difference between AMP and best price (with certain exceptions). Section 2501(b) of the ACA increases the URA for generic drugs to 13 percent of the AMP.

[32] Section 1927(c)(2) of the Act.

participating manufacturers owe by multiplying the URA for a specific drug by the number of units of that drug dispensed to Medicaid beneficiaries in that quarter.

Related OIG Work

A February 2009 OIG report compared pharmacy reimbursement under Medicare Part D and Medicaid for 79 drugs.[33] It did not compare total program expenditures and did not determine the impact of rebates. The report found that, nationally, the average pharmacy reimbursement amounts for both programs were similar for most selected brand-name drugs. The report also found that nationally, Medicaid pharmacy reimbursement amounts typically exceeded those in Part D for selected generic drugs.

A March 2011 OIG report examined manufacturer rebates under Part D.[34] That report found that sponsors reported receiving $6.5 billion in drug manufacturer rebates in 2008. These rebates should reduce the cost of the Part D program. However, the report also found that sponsors underestimated rebates in 69 percent of their bids for plan year 2008, causing beneficiary premiums and Government payments to be higher than they otherwise would have been.

METHODOLOGY

Scope

For this review, we compared pharmacy reimbursement and rebates under Medicare Part D and Medicaid for selected high-expenditure brand-name and generic drugs (i.e., NDCs). We selected these drugs based on PDE data from both PDP and MA-PD sponsors. We selected the 100 brand-name drugs with the highest Part D expenditures in retail pharmacies in 2009 and the 100 generic drugs with the highest Part D expenditures in retail pharmacies in 2009. Part D expenditures for these 200 drugs totaled $27 billion ($24 billion for brand-name drugs and $3 billion for generic drugs). Medicaid expenditures for these

[33] OIG, *Comparing Pharmacy Reimbursement: Medicare Part D to Medicaid*, OEI-03-07-00350.

[34] OIG, *Concerns With Rebates in the Medicare Part D Program*, OEI-02-08-00050.

200 drugs totaled $6.8 billion ($6.4 billion for brand-name drugs and $449 million for generic drugs).[35]

Data Collection

Medicare Part D. We obtained PDE records from CMS for all covered drugs dispensed in retail pharmacies with dates of service in 2009 and aggregated these data to identify expenditures by NDC. We determined whether a drug was brand-name or generic using drug type information from two national drug compendia (Redbook and First DataBank), as well as Medicaid drug product data. We used data from the National Council of Prescription Drug Programs (NCPDP) that identify the primary pharmacy type to limit PDE records to drugs dispensed in retail pharmacies.[36] We then identified the top NDCs (100 brand-name drugs, 100 generic drugs) by total Part D expenditures (i.e., the sum of the ingredient cost and dispensing fee) based on these PDE claims data. The 200 selected NDCs were associated with 44 manufacturers.

Medicaid. We obtained State Medicaid payment, utilization, and dispensing fee data for 2009 from CMS. Using these files, we determined State Medicaid agencies' expenditures for and utilization of the 200 drugs identified above.

Rebates. To obtain Medicare Part D rebate data, we sent letters to the 44 manufacturers of the 200 selected drugs in December 2010. We asked them to report how much they paid in Part D rebates, by NDC, to Part D sponsors in 2009 for drugs dispensed in retail pharmacies. All manufacturers provided rebate data.[37]

Several manufacturers that paid Part D rebates were unable to limit their rebate data to drugs dispensed in retail pharmacies. Some of these provided estimates of rebates based on utilization; others did not provide these estimates. For drugs sold by manufacturers that did not provide actual or estimated retail-specific data, we calculated rebate estimates ourselves. To do this, we used PDE data to calculate what

[35] According to summary data for individual NDCs, Part D expenditures for these 200 drugs accounted for almost half of program expenditures for drugs dispensed in retail pharmacies in 2009 and Medicaid expenditures for these 200 drugs accounted for about 30 percent of program expenditures in 2009.

[36] A retail pharmacy has a dispenser type classification of "01" in NCPDP data.

[37] Manufacturers of eight of the selected brand-name drugs reported that either (1) they do not provide rebates for these drugs or (2) these drugs are not dispensed in retail pharmacies.

percentage of a drug's utilization was dispensed through retail pharmacies and calculated rebates proportionally.

For Medicaid rebates, we obtained 2009 quarterly URAs from CMS for each of the drugs under review to calculate total rebates. URAs include both the basic and additional rebates (where applicable).

Data Analysis

Pharmacy reimbursement amounts. We first compared 2009 pharmacy reimbursement of sponsors with that of State Medicaid agencies. To do this, we calculated the average Part D and Medicaid unit reimbursement amounts for each of the selected drugs by dividing total expenditures (ingredient costs and dispensing fees) by the total quantity dispensed. We calculated the percentage differences in pharmacy reimbursement between Medicare Part D and Medicaid for each brand-name drug and each generic drug under review and compared these differences. Additionally, we calculated the median percentage differences in pharmacy reimbursement between Medicare Part D and Medicaid for all brand-name drugs and all generic drugs under review.

Manufacturer rebates. We then calculated and compared Part D and Medicaid rebates. We calculated total 2009 Part D rebates for the 200 drugs based on manufacturer submissions and then determined a unit rebate amount for each drug by dividing total rebates by quantity dispensed. For Medicaid, we calculated total 2009 rebates by multiplying the quarterly URAs[38] by quarterly utilization for each drug and adding these totals. We calculated a single Medicaid unit rebate amount in 2009 for each drug by dividing total rebates by quantity dispensed. We then determined the percentage differences in unit rebate amounts between the two programs for each brand-name and each generic drug under review and compared these differences. We also calculated the median percentage differences in rebates between the two programs for all brand-name and all generic drugs under review.

To gain further insight into the differences between Part D and Medicaid rebates, we determined whether the manufacturers of the brand-name drugs under review paid inflation-based rebates to States in addition to the basic Medicaid rebates. To do this, we calculated the

[38] "URA" refers to CMS's calculated amount to determine rebates; "unit rebate amount" hereinafter refers to OIG's calculation of a volume-weighted average in 2009 of the quarterly URAs.

quarterly basic rebate amount for each brand-name drug (i.e., 15.1 percent of AMP or the difference between AMP and best price) and subtracted it from the drug's quarterly URA. The difference was the amount of additional rebate that was owed because the drug's price increased faster than the rate of inflation.

Net costs. Finally, we determined the effect of differences in pharmacy reimbursement and rebates on expenditures by calculating net costs under each program. To calculate net costs, we subtracted unit rebate amounts from unit reimbursement amounts for each drug under review. We calculated the percentage differences in net unit costs between Medicare Part D and Medicaid for each drug under review and compared these differences. We also calculated the median percentage differences in net costs between Medicare Part D and Medicaid for all brand-name drugs and all generic drugs under review.

Limitations

The findings in this report apply only to the 200 drugs we reviewed and are not projectable to all drugs covered under Part D and Medicaid. We did not verify the accuracy or completeness of CMS's Part D PDE data; CMS's Medicaid utilization data; manufacturer rebate submissions; CMS's Medicaid rebate data; pharmacy classifications; or drug type data from CMS, Redbook, or First DataBank.

The prices that serve as the bases for Medicaid rebate data (i.e., AMPs and best prices) are subject to revision. Therefore, the findings in this report are based on rebate data available at the time of the analysis. Part D and Medicaid rebate data are confidential; consequently, all of our findings are reported in the aggregate.[39] Additionally, we did not collect data on supplemental rebates negotiated by States, nor did we include them in the analysis.

Several manufacturers that paid Part D rebates were unable to limit their rebate data to drugs dispensed in retail pharmacies. In these cases, the manufacturers either provided estimates of these rebates or we calculated estimates based on reported rebates for drugs dispensed to all sources.

[39] Additionally, § 3313(b)(2)(B) of the ACA prohibits OIG from publishing proprietary information in this report.

The ACA changed the definition of AMP as well as the URA for Medicaid drug rebates. In addition, provisions in the ACA increased Medicaid rebate percentages and additional Part D price reductions on certain brand-name drugs for certain beneficiaries in 2011.[40] However, these provisions were not in effect during the period under review.

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.

[40] Section 3301 of the ACA established a drug discount program for Part D beneficiaries that have entered the coverage gap (i.e., the period when a beneficiary is responsible for paying 100 percent of his or her drug costs), effective January 1, 2011.

FINDINGS

In 2009, pharmacy reimbursement amounts under Medicare Part D and Medicaid were similar for most selected brand-name drugs but differed substantially for over half of selected generic drugs

Part D sponsors and State Medicaid agencies paid pharmacies similar amounts for most of the selected brand-name drugs.[41] However, for most of the generic drugs under review, differences in pharmacy reimbursement between the two programs were much greater.

Pharmacy reimbursement amounts differed by less than 2 percent for over two-thirds of brand-name drugs

For 70 of the 100 brand-name drugs under review, the difference between the average Part D and Medicaid unit reimbursement amounts was less than 2 percent. Pharmacy reimbursement differed by less than 10 percent for an additional 20 drugs. Only 5 of the 100 brand-name drugs had a difference in pharmacy reimbursement that exceeded 25 percent.[42]

As Figure 1 illustrates, for all 30 drugs for which the reimbursement difference exceeded 2 percent, it was Medicaid that paid more. Overall, Medicaid reimbursement was higher for 63 drugs; Part D reimbursement was higher for the remaining 37. At the median, Medicaid reimbursement amounts to pharmacies were 1 percent higher than the Part D amounts for brand-name drugs.

Pharmacy reimbursement amounts differed by more than 15 percent for over half of generic drugs

As Figure 2 illustrates, pharmacy reimbursement amounts under Part D and Medicaid differed by more than 15 percent for 53 of the 100 generic drugs under review. In fact, the difference in pharmacy reimbursement for 28 of these drugs exceeded 25 percent (6 of these drugs had differences that exceeded 50 percent).[43] Overall, Medicaid reimbursement was higher for 62 of these drugs; Part D reimbursement was higher for the remaining 38.[44] At the median, Medicaid

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[41] This is generally similar to the results of our previous price comparison issued in 2009. See OIG, *Comparing Pharmacy Reimbursement: Medicare Part D to Medicaid*, OEI-03-07-00350.

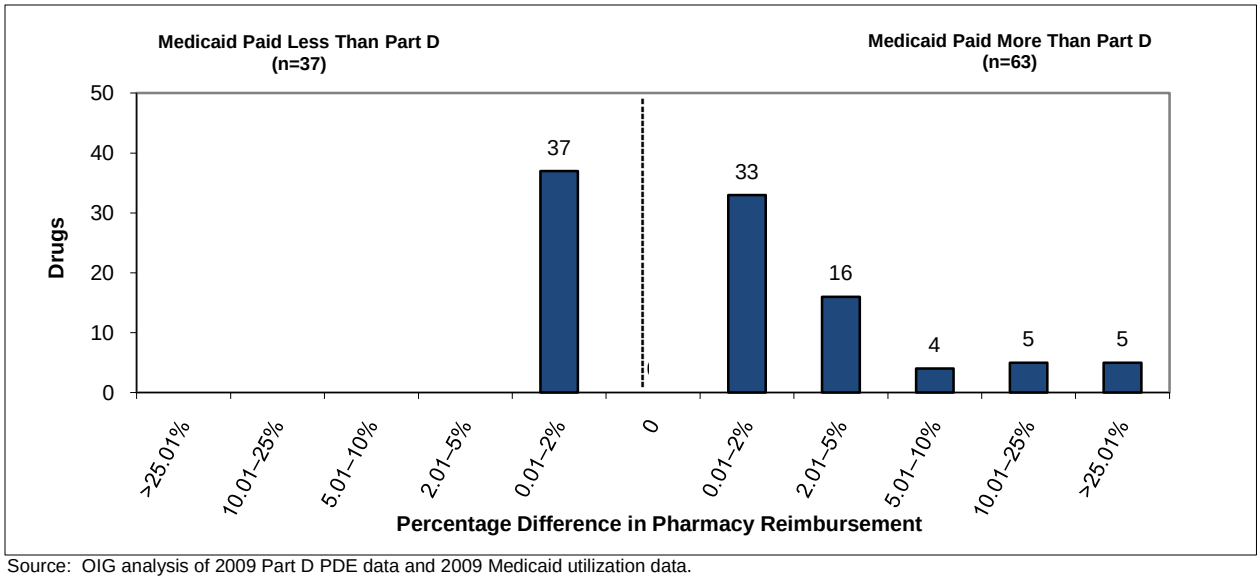
[42] Medicaid paid between 32 and 52 percent more than Part D paid for these five drugs.

[43] Medicaid paid between 57 and 138 percent more than Part D paid for four of these drugs. For the remaining two drugs, Medicaid paid 51 and 53 percent less than Part D.

[44] Although differences in reimbursement for most of these drugs exceeded 15 percent, in actual dollar terms, the differences were typically less than $0.25 per unit.

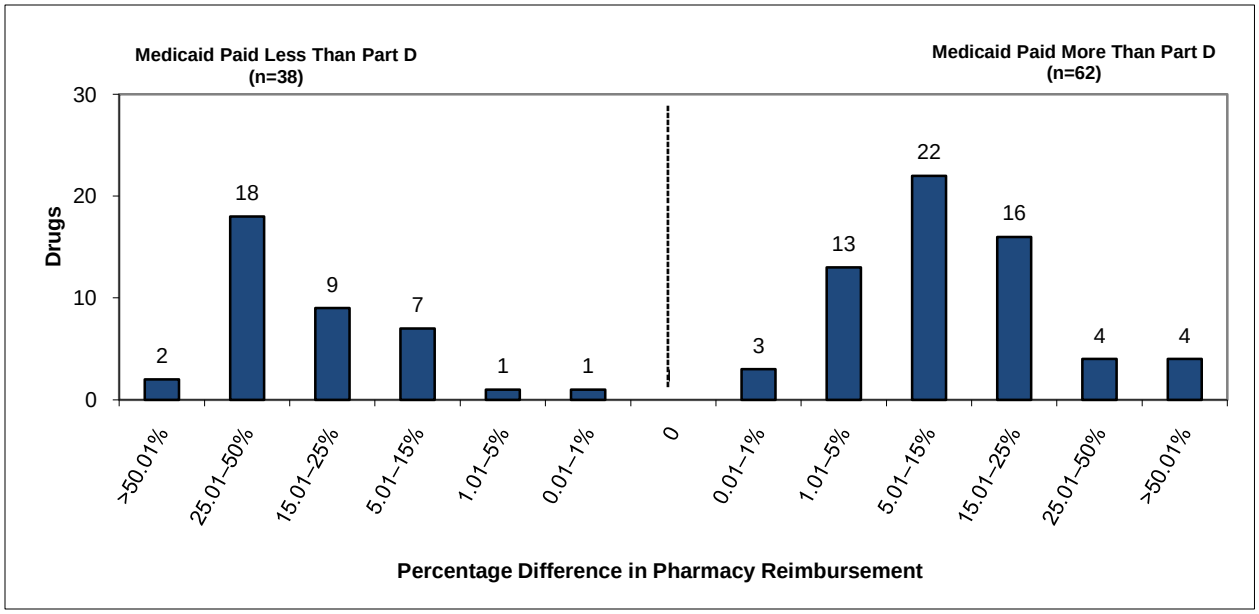
reimbursement amounts were 3 percent higher than Part D amounts for selected generic drugs.

Figure 1. Comparison of Unit Reimbursement Amounts in 2009 for the 100 Brand-Name Drugs Under Review



Source: OIG analysis of 2009 Part D PDE data and 2009 Medicaid utilization data.

Figure 2. Comparison of Unit Reimbursement Amounts in 2009 for the 100 Generic Drugs Under Review

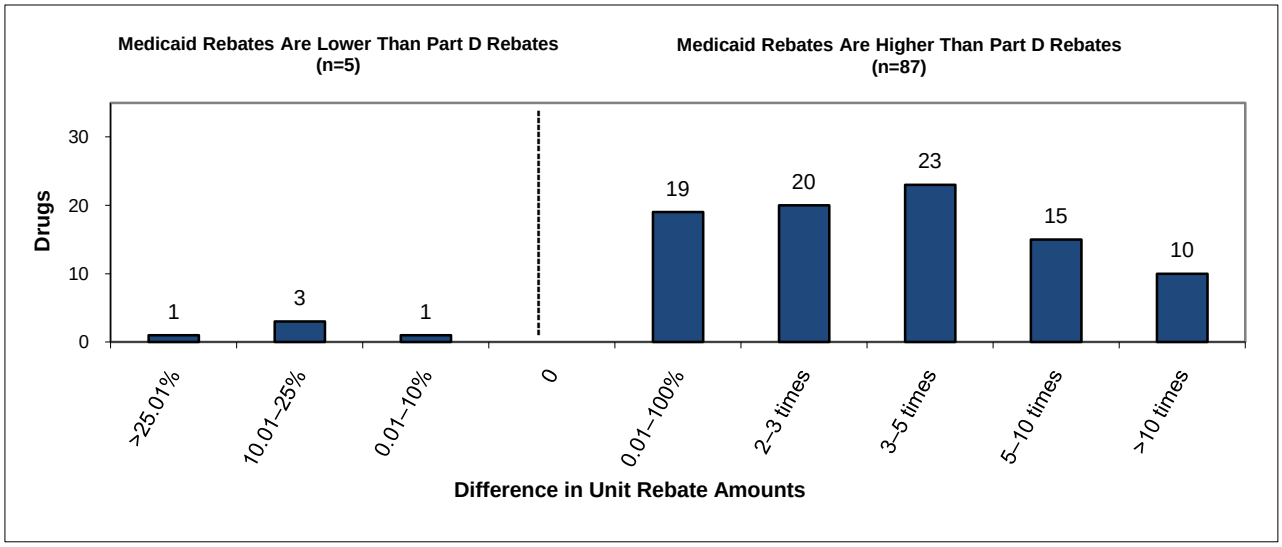


Source: OIG analysis of 2009 Part D PDE data and 2009 State Medicaid utilization data.

In 2009, Medicaid unit rebate amounts for brand-name drugs were substantially higher than Part D unit rebate amounts; rebates for generic drugs under both programs were negligible

Overall, Medicaid unit rebate amounts were 3 times greater than Part D unit rebate amounts at the median for the 100 brand-name drugs under review. For 68 of these drugs, manufacturers paid at least twice as much per unit in Medicaid rebates in 2009 compared to amounts paid per unit under Part D (Medicaid unit rebate amounts were over 10 times greater than Part D unit rebate amounts for 10 of these drugs). Manufacturers for an additional eight brand-name drugs responded that they did not provide any Part D rebates in 2009 (Medicaid rebates for these drugs ranged from 16 to 54 percent of the unit costs for those drugs). Conversely, Part D unit rebate amounts exceeded Medicaid unit rebate amounts for just five of the brand-name drugs under review. Figure 3 illustrates the substantial difference in rebate amounts for Part D and Medicaid.[45]

Figure 3. A Comparison of Unit Rebate Amounts for Brand-Name Drugs



Source: OIG analysis of 2009 Part D rebate data and 2009 Medicaid rebate data.

Unlike rebates for brand-name drugs, rebates for generic drugs had little impact in reducing net expenditures. Part D sponsors collected virtually no rebates for generic drugs, according to manufacturer rebate

[45] Figure 3 includes only the 92 drugs for which there were both Medicaid and Part D rebates, thus enabling us to calculate the percentage difference. Manufacturers for the remaining eight brand-name drugs reported either (1) that they do not provide Part D rebates for these drugs or (2) that these drugs were not dispensed in retail pharmacies.

data. Although manufacturers pay Medicaid rebates for generic drugs, they reduced total expenditures for the 100 generic drugs under review by only 3 percent. For individual generic drugs, Medicaid rebates ranged from less than 1 percent to 9 percent of reimbursement.[46] The small amount of Medicaid expenditures and rebates attributed to generic drugs is due to the fact that the AMPs, on which rebates are based, for generic drugs are often much less than actual Medicaid reimbursement amounts.

Medicaid rebates were substantially higher than Part D rebates for brand-name drugs because manufacturers for virtually all brand-name drugs under review paid inflation-based rebates

From 1996 through 2009, the basic URA for a brand-name drug was the greater of 15.1 percent of the AMP or the difference between the AMP and best price. In addition, if the AMP for a brand-name drug rose faster than inflation, then the drug's manufacturer was (and still is) required to pay an additional rebate over and above the basic URA. For 98 of the 100 brand-name drugs under review, manufacturers paid this additional rebate in all 4 quarters of 2009.[47]

The inflation-based additional rebate is the primary reason Medicaid rebates are substantially higher than Part D rebates. In the aggregate, 55 percent of the total Medicaid rebates owed by manufacturers for the 100 brand-name drugs under review ($1.6 billion out of $2.9 billion) are owed because AMPs rose faster than inflation. For 70 of the brand-name drugs, the additional rebate portion of the URA (i.e., the inflation-based amount) actually exceeded the basic rebate portion (i.e., either 15.1 percent of the AMP or the difference between the AMP and best price). The additional unit rebate amounts alone exceeded the Part D unit rebate amounts for 69 brand-name drugs[48] under review and were at least two times more than the Part D rebate amounts for 38 of these drugs.

[46] CMS's rebate data did not contain rebate amounts for one of the selected generic drugs. We excluded the drug from this portion of the analysis.

[47] The manufacturer of one of the remaining two drugs paid the additional rebate for that drug in three of four quarters of 2009; the manufacturer for the other drug did not pay any additional rebates for that drug in 2009.

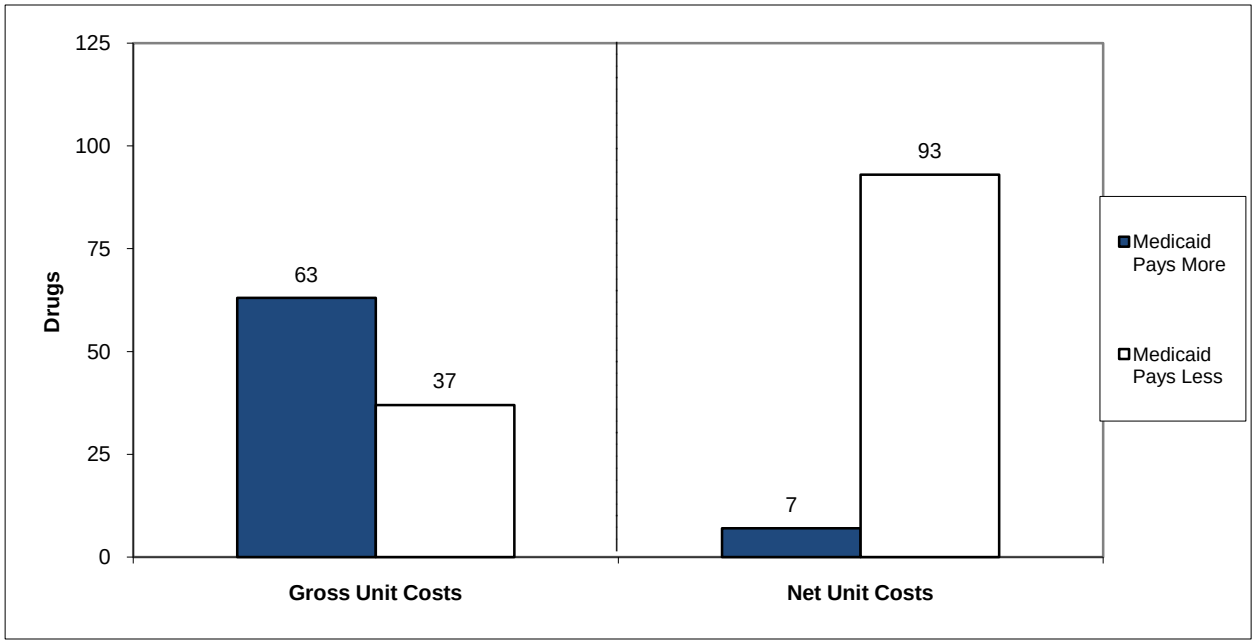
[48] This total does not include the eight brand-name drugs for which the manufacturers reported either (1) that they do not provide Part D rebates for these drugs or (2) that these drugs were not dispensed in retail pharmacies.

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 brand-name drugs under review were similar, Medicaid unit rebates for these drugs were substantially higher than those under Part D. Consequently, Medicaid's net unit costs (i.e., pharmacy reimbursement minus rebates) were much lower (34 percent at the median) than net unit costs under Part D in 2009.

As previously stated, Medicaid unit reimbursement amounts were actually higher than Part D unit reimbursement amounts for 63 brand-name drugs. However, after accounting for rebates, Medicaid net unit costs were higher than Part D net unit costs for only 7 drugs; Part D net unit costs exceeded Medicaid net unit costs for the remaining 93. In fact, Medicaid net unit costs were more than 25 percent below Part D net unit costs for nearly three-fourths of these brand-name drugs. Figure 4 illustrates the effect of rebates on drugs costs.

Figure 4. Comparison of Average Medicare Part D and Medicaid Net and Gross Costs for Brand-Name Drugs



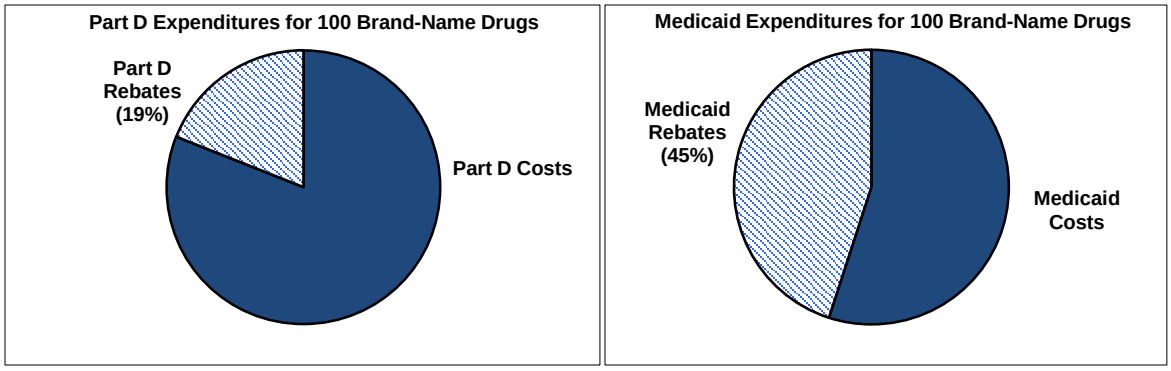
Source: OIG analysis of 2009 Part D PDE data, Part D manufacturer rebates, Medicaid utilization data, and Medicaid rebates.

Medicaid collected nearly two-thirds as much in rebates as Part D despite having only one-fourth of the expenditures

As further evidence of Medicaid's substantially higher unit rebate amounts, Medicaid collected nearly two-thirds as much in rebates as Part D ($2.9 billion vs. $4.5 billion) for the selected brand-name drugs despite having only about one-fourth of the expenditures ($6.4 billion vs. $24 billion).

Overall, rebates reduced Part D expenditures by 19 percent for the 100 brand-name drugs under review (from $24 billion to $19.5 billion) in 2009. Medicaid rebates accounted for a substantially higher percentage of total expenditures, reducing Medicaid spending for the 100 drugs under review by 45 percent (from $6.4 billion to $3.5 billion). See Figure 5 for an illustration on the effect of rebates on expenditures for brand-name drugs.

Figure 5. Rebates as a Percentage of Expenditures Under Part D and Medicaid



Source: OIG analysis of 2009 Part D PDE data, manufacturer rebate data, 2009 Medicaid utilization data, and Medicaid rebate data.

CONCLUSION

Prescription drug rebates reduce the program costs of both Medicare Part D and Medicaid. Medicaid rebates are defined by statute; additional rebates are required when prices for brand-name drugs increase faster than inflation. Unlike the Medicaid program, Part D sponsors (or contractors acting on their behalf) negotiate rebates with drug manufacturers without any statutory requirements on rebate amounts. 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.

In this review, we found that Part D sponsors and State Medicaid agencies paid pharmacies similar amounts for most brand-name drugs under review. However, statutorily defined Medicaid unit rebate amounts for brand-name drugs exceeded Part D unit rebate amounts by a substantial margin. As a result, Medicaid collected nearly two-thirds as much as Part D in rebates for the 100 brand-name drugs ($2.9 billion vs. $4.5 billion), despite having only about one-fourth of the expenditures ($6.4 billion vs. $24 billion).

Despite Part D's larger market share (including dual eligible beneficiaries who once received drug coverage under Medicaid), Part D does not collect as much in rebates that reduce program expenditures. A major driver of the higher Medicaid rebates was the additional amount owed when prices for brand-name drugs increase faster than inflation. This not only produces additional Medicaid rebates, but also helps protect the program from increased costs when manufacturers raise prices.

Furthermore, Medicaid rebates for brand-name drugs may increase as a result of the ACA provisions that raise the rebate percentage. Given the potential impact on beneficiary and Government expenditures, we believe that it is important for CMS to continually examine any differences in how each program collects rebates.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS agreed with our overall findings. CMS stated that it was pleased OIG confirmed that the Medicaid rebate program is working well and providing substantial rebates to offset the high costs of prescription drugs. CMS agreed that the ACA may further increase Medicaid

rebates for brand-name drugs and that it is important to continue to examine the differences in how each program collects rebates.

We did not make any changes to the report based on 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

Deputy Administrator
Baltimore, MD 21244-1850

DATE: JUL 1 5 2011

TO: Daniel R. Levinson
Inspector General

/S/

FROM: Marilyn Tavenner
Principal Deputy Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D (OEI-03-10-00320)

Thank you for the opportunity to review and comment on the subject OIG Draft Report entitled: "Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D" (OEI-03-10-00320). This report was required by Section 3313(b), Study and Report on Prescription Drug Prices Under Medicare Part D and Medicaid, of the Affordable Care Act. This report compares pharmacy reimbursement and manufacturer rebates under Medicare Part D to Medicaid for the 100 brand-name and 100 generic drugs with the highest Part D expenditures using 2009 data. This report also compares each program's net drug costs and examines the effect that differences may have on overall program costs. The Centers for Medicare & Medicaid Services (CMS) agrees with the overall findings in the OIG report acknowledging the efforts CMS has made to improve lowering the costs in the Medicaid drug program.

CMS was pleased the OIG confirmed that the Medicaid rebate program is working well, and providing substantial rebates to offset the cost of the high costs of prescription drugs. CMS also acknowledges that the OIG correctly attributed differences in cost to statutory requirements regarding rebates in Medicaid and Medicare Part D. Unlike in the Medicaid program, Part D sponsors (or contractors acting on behalf of sponsors) negotiate rebates with drug manufacturers without any statutory requirements on rebate amounts, and the Government is expressly prohibited from instituting a price structure for the reimbursement of covered Part D drugs. Additionally, we agree with the OIG that the Affordable Care Act may further increase brand name drug rebates in the Medicaid program and that it is important for CMS to continually examine the differences in how each program collects rebates.

We would like to thank the OIG for their efforts in reviewing pharmacy reimbursement and rebates under Medicare Part D and Medicaid and look forward to working with the OIG on this and other issues in the future.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director of the Medicare and Medicaid Prescription Drug Unit.

Edward K. Burley served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to the report include Daniel J. Mallinson; central office staff who contributed include Eddie Baker, Jr., and Kevin Manley.

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