Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM

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EXECUTIVE SUMMARY

OBJECTIVES

1. To determine the extent to which all Part D sponsors received rebates in 2008.
2. To determine the extent to which all Part D sponsors passed rebates on to beneficiaries.
3. To describe the nature of the rebates received by selected sponsors.
4. To describe the nature of selected sponsors' contractual relationships with pharmacy benefit managers (PBM).

BACKGROUND

Under the Medicare Part D program, private insurance companies, known as sponsors, provide drug coverage to beneficiaries who choose to enroll. These sponsors are responsible for reducing the cost of the program by negotiating rebates from drug manufacturers. Drug manufacturers provide rebates to increase drug sales.

Rebates can substantially reduce the cost of the Part D program; however, sponsors must accurately report these rebates for the Government and beneficiaries to receive any cost savings. Prior to this review, little information was publicly available about the extent to which sponsors receive rebates for Part D drugs and pass them on to the Government and beneficiaries. Also, little was known about the nature of rebates and the contractual relationships between sponsors and PBMs, the third-party entities that often negotiate for rebates on behalf of sponsors.

Before the beginning of each plan year, sponsors must provide the Centers for Medicare & Medicaid Services (CMS) with bids that contain information about the rebates they expect to receive. CMS uses these bids to calculate beneficiary premiums. After the close of the plan year, sponsors must provide CMS with information about the actual amount of rebates they received. CMS uses this information to determine the amount that the Government ultimately pays each sponsor for providing the benefit. If sponsors receive rebates at the sponsor level, rather than the plan level, CMS requires that sponsors allocate a portion of these rebates to each of their plans. The methods sponsors use can affect the amounts that the Government ultimately pays sponsors for providing the benefit.

We based this study on a review of all Part D sponsors' Direct and Indirect Remuneration Reports for Payment Reconciliation (hereinafter referred to as rebate reports) for 2008, Prescription Drug Event data for 2008, all sponsors' bids for 2008, contracts from six selected sponsors, and structured interviews with these six sponsors.

FINDINGS

Medicare Part D sponsors reported receiving $6.5 billion in drug manufacturer rebates in 2008. On average, this equaled $275 per beneficiary, or about $7 per drug dispensed in 2008. These rebates were approximately 10 percent of total gross Part D drug costs, which were $63 billion in 2008. Some sponsors reported large differences in rebates across their plans. How sponsors allocate rebates across their plans may affect the amount that the Government ultimately pays sponsors for providing the benefit.

Sponsors commonly underestimated rebates in their bids, which led to higher beneficiary premiums. Sponsors underestimated rebates in 69 percent of their bids for plan year 2008. When sponsors underestimate rebates in their bids, beneficiary premiums are higher than they otherwise would be and both the Government and beneficiaries overpay for the benefit. Although the Government recoups some of the overpayments, beneficiaries do not.

Selected sponsors received rebates when they encouraged beneficiaries to use certain drugs. The six sponsors we reviewed received two distinct types of rebates: formulary rebates and market-share rebates. Formulary rebates were provided when sponsors' formularies encouraged beneficiaries to use certain drugs over others, whereas market-share rebates were based on the total number of the rebated drugs that beneficiaries used compared to the total number of other drugs used.

Selected sponsors had complex contractual relationships with PBMs that sometimes lacked transparency. CMS holds sponsors ultimately responsible for accurately reporting rebates and for ensuring that their PBMs comply with CMS requirements. The lack of transparency raises concerns that sponsors may not always have enough information to oversee the services and information provided by PBMs. In addition, the selected sponsors reported that their PBMs collected fees from drug manufacturers that were not always passed on to the Part D program.

RECOMMENDATIONS

Because of the size of these rebates, it is vital that rebates be reported accurately and that the Government and beneficiaries receive the full benefit of these rebates. Our review identified several concerns about these rebates. Based on these findings, we recommend that CMS:

Take steps to ensure that sponsors more accurately include their expected rebates in their bids. After the close of each plan year, CMS should compare the actual rebates that sponsors reported to the rebates in sponsors' bids. CMS should work with the sponsors that have particularly large differences to ensure that these differences do not occur in the future. CMS should also consider targeting these sponsors in its financial audits.

Require sponsors to use methods CMS deems reasonable to allocate rebates across plans. The method sponsors use to allocate rebates across plans may affect the amount that the Government pays for the Part D program. In its guidance for reporting 2009 rebates, CMS provides a list of allocation methods it considers reasonable, such as allocating rebates based on drug utilization or spending. CMS should require sponsors to either use one of the methods it determines to be reasonable or submit documentation proving that an alternative method is reasonable.

Ensure that sponsors have sufficient audit rights and access to rebate information. Sponsors are ultimately responsible for accurately reporting their rebates to CMS. CMS should ensure that sponsors have sufficient information to accurately report rebates. To do this, CMS could require sponsors to have stronger provisions in their contracts related to their audit rights and access to rebate information. CMS could also provide more detailed guidance to sponsors about how they should monitor PBM rebate information.

Ensure that sponsors appropriately report the fees that PBMs collect from manufacturers. CMS should clarify when these fees should be reported as rebates. In addition, beginning for plan year 2009, CMS required sponsors to report all payments that meet the definition of "bona fide service fees," including those that the PBM retains and does not share with the sponsor. CMS should use this information to monitor the fees and ensure that they were reported appropriately.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with one of our recommendations in the draft report and partially concurred with another. CMS did not concur with the remaining two recommendations.

CMS concurred with our first recommendation, to ensure that sponsors more accurately include rebates in their bids. CMS stated that it will consider adding to its bid review a comparison of the rebates sponsors actually receive to the rebates they report in their bids.

CMS did not concur with our second recommendation, to require sponsors to use certain methods to allocate rebates across plans. CMS stated that it currently requires sponsors to use a reasonable allocation methodology that reflects differences in utilization and spending. However, our findings show that sponsors may be inappropriately allocating rebates across plans. Because this may result in a loss to the Government, we continue to recommend that CMS require sponsors to use allocation methods it deems reasonable. In our final report, we reworded the recommendation and added a sentence recommending that if sponsors choose an alternative method, they must submit documentation proving that it is reasonable.

CMS did not concur with our third recommendation, to require sponsors to have sufficient audit rights and access to rebate information. It stated that it believes the current regulatory framework strikes the appropriate balance to encourage sponsors to negotiate sufficient disclosure of information from their PBMs, while recognizing the PBMs' view that certain information is highly confidential. We are aware of the current regulatory framework and the importance of balancing the interests of sponsors and PBMs. However, this report shows that some Part D sponsors have limited rights to audit their PBMs and limited access to information about their rebates. In response to CMS's comments, we modified our recommendation and offered two ways for CMS to ensure that sponsors have sufficient audit rights and access to rebate information.

CMS partially concurred with our fourth recommendation, to ensure that sponsors appropriately report the fees that PBMs collect from manufacturers. CMS noted that it does not concur that more specificity is required in the definition of "bona fide service fees." However, this report shows that sponsors are reporting these fees differently. While

CMS may not need to change the definition of "bona fide service fees," it may need to provide additional guidance or clarification about when sponsors need to report these fees as rebates.

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INTRODUCTION

OBJECTIVES

1. To determine the extent to which all Part D sponsors received rebates in 2008.
2. To determine the extent to which all Part D sponsors passed rebates on to beneficiaries.
3. To describe the nature of the rebates received by selected sponsors.
4. To describe the nature of selected sponsors' contractual relationships with pharmacy benefit managers (PBM).

BACKGROUND

The Medicare Part D program provides an optional prescription drug benefit to Medicare beneficiaries.[1] Under the program, private insurance companies, known as sponsors, provide drug coverage to beneficiaries who choose to enroll. These sponsors are responsible for reducing the cost of the program by negotiating rebates from drug manufacturers. Drug manufacturers provide rebates to increase drug sales.

Rebates can substantially reduce the cost of the Part D program; however, sponsors must accurately report these rebates for the Government and beneficiaries to receive any cost savings. Prior to this review, little information was publicly available about the extent to which sponsors receive rebates for Part D drugs and pass them on to the Government and beneficiaries. Also, little was known about the nature of rebates and the contractual relationships between sponsors and PBMs, the third-party entities that often negotiate rebates on behalf of sponsors.[2]

The Medicare Part D Benefit

Under Medicare Part D, sponsors may offer stand-alone prescription drug plans (PDP) or they may offer prescription drug coverage as part of a Medicare Advantage Prescription Drug Plan (also known as an

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

[2] PBMs can provide a variety of services to sponsors to help manage their prescription drug benefit. These services include processing prescription drug claims, contracting with pharmacies, managing formularies, as well as negotiating rebates with drug manufacturers. PBMs can be compensated for these services in a variety of ways, including receiving a fixed payment per claim or retaining a percentage of sponsors' rebates.

MA-PD plan). Sponsors typically offer drug coverage under multiple plans. These plans may differ in their benefit design, such as the specific drugs they cover and the copayments they charge, or they may differ in the geographic regions they cover.

Sponsors are required to offer, at a minimum, a basic prescription drug benefit that is either the defined standard prescription drug benefit or is "actuarially equivalent" to the standard benefit.[3] Most beneficiaries are responsible for certain costs, which may include a monthly premium, an annual deductible, and coinsurance or copayments. However, certain low-income beneficiaries are eligible to receive a subsidy that pays some or all of these costs.[4]

For each of their plans, sponsors develop a list of covered drugs, known as a formulary. A formulary often gives preference to certain drugs over other drugs that treat the same condition. The drugs on each formulary are organized into broad therapeutic categories and subsets called pharmacologic classes. Each formulary must include at least two drugs within each category or class. In addition, each formulary must include "all or substantially all" drugs in six categories, which are often referred to as protected classes.[5] Beginning in 2011, however, sponsors are required to include on their formularies all drugs in categories and classes that CMS identifies as being of clinical concern.[6] CMS is currently determining how it will identify these categories and classes.

Sponsors can also use other methods to give preference to certain drugs over others. These methods—called utilization management tools—place restrictions on the use of certain drugs on their formularies. For example, sponsors may require a beneficiary to seek prior authorization before he or she is able to receive a certain drug. Sponsors may also

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[3] 42 U.S.C. § 1395w-102 and 42 CFR §§ 423.104(d) and (e). "Actuarially equivalent" means that the plan's benefits must be of a dollar value equivalent to that of the standard benefit.

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

[5] The six protected classes include the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes. See 42 CFR § 423.120(b)(2)(i); Centers for Medicare & Medicaid Services (CMS), *Prescription Drug Benefit Manual*, ch. 6, § 30.2.5. Accessed at http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/R2PDBv2.pdf on October 1, 2009.

[6] The Patient Protection and Affordable Care Act requires that CMS establish criteria to select the categories and classes of drugs it will consider as being of clinical concern. See P.L. 111-148 § 3307 and 75 Fed. Reg. (Apr. 15, 2010), pp. 19766–19767.

require a beneficiary to try a less expensive alternative before progressing to a costlier drug.

Price Concessions and Drug Manufacturer Rebates

The Part D program relies on sponsors to negotiate drug manufacturer rebates and other price concessions to reduce the cost of the program to beneficiaries and the Government. Price concessions are payments that decrease sponsors' drug costs.[7] Rebates from drug manufacturers are the most common type of price concessions. Other types of price concessions include discounts, coupons, and other concessions that reduce the cost of drugs. For example, if a sponsor received a payment from a pharmacy because of a risk-sharing or prompt payment agreement or a payment from a pharmaceutical manufacturer for a legal settlement, the payment is considered a price concession.[8]

Sponsors pass rebates and other types of price concessions on to beneficiaries and the Government in several ways. Sponsors must include expected rebates and other price concessions in their bids, which lowers the premiums beneficiaries pay for drug coverage (as discussed below). Sponsors may pass the cost savings derived from rebates directly on to beneficiaries at the time they purchase drugs; these are called point-of-sale rebates.[9] Additionally, sponsors pass rebates on to the Government by reporting their actual rebates to CMS, which uses them to adjust Part D payments in a process called payment reconciliation.[10]

Reporting of Drug Manufacturer Rebates to CMS

Before the beginning of the plan year, sponsors must provide CMS with information about all rebates that they expect to receive as a part of their bids.[11] These bids provide CMS with an estimate of the cost to provide the benefit to each beneficiary. CMS uses bids to calculate beneficiary premiums for each plan. Any anticipated rebates sponsors

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[7] 42 CFR § 423.308.

[8] CMS, *Final Medicare Part D DIR Reporting Requirements for 2008 Payment Reconciliation*, June 8, 2009, pp. 4, 6, and 7.

[9] 70 Fed. Reg. 4195, 4244 (Jan. 28, 2005).

[10] 42 CFR §§ 423.315 and 423.343.

[11] Specifically, sponsors must include in their bids all price concessions that are not passed on to the beneficiary at the point of sale. See CMS, *Instructions for Completing the Medicare Prescription Drug Plan Bid Pricing Tool for Contract Year 2008*, April 2007, p. 26.

report to CMS in the bids reduce beneficiary premiums.[12] CMS also uses the bids to calculate the monthly payments it makes to each sponsor for providing the benefit. When sponsors underestimate rebates in their bids, both the Government and beneficiaries overpay for the benefit. The Government recoups some, but not all, of the overpayments in a process known as reconciliation. Beneficiaries do not recoup any of the money that they pay in higher premiums.

During reconciliation, CMS compares the monthly payments it makes to the sponsor and the premiums charged to beneficiaries to the sponsor's costs. To do this, CMS requires sponsors to provide information about the actual rebates they receive in reports known as Direct and Indirect Remuneration (DIR) Reports for Payment Reconciliation (hereinafter referred to as rebate reports).[13] The rebate amounts sponsors report reduce the amounts the Government pays the sponsors for providing the benefit.[14] Sponsors must submit one rebate report for each plan. Sponsors must include all of the rebates and other price concessions that they receive, as well as any rebates that the PBMs retained.[15] Sponsors are not required to report administrative fees that PBMs collect from manufacturers if the fees meet certain conditions.[16]

If sponsors receive rebates at the sponsor level, rather than the plan level, CMS requires that sponsors allocate a portion of these rebates to each of their plans using a "reasonable" methodology. In its guidance for reporting 2009 rebates, CMS provided examples of allocation methodologies it considers reasonable, but it did not require sponsors to

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[12] 42 U.S.C. § 1395w-113.

[13] For example, see CMS, *Final Medicare Part D DIR Reporting Requirements for 2008 Payment Reconciliation*, June 8, 2009, p. 1. See also U.S.C. § 1395w-115(f)(1)(A).

[14] For more information about payment reconciliation, see Office of Inspector General (OIG), *Medicare Part D Reconciliation Payments for 2006 and 2007* (OEI-02-08-00460), September 2009.

[15] If sponsors have not received all of their rebates at the time of reporting, they must report estimates of the amounts they expect to receive. See CMS, *Final Medicare Part D DIR Reporting Requirements for 2008 Payment Reconciliation*, June 8, 2009, p. 11.

[16] According to CMS guidance, sponsors are not required to report administrative fees that PBMs collect and retain if the fees are for bona fide services and are at fair market value. See CMS, *Final Medicare Part D DIR Reporting Requirements for 2008 Payment Reconciliation*, June 8, 2009, p. 7.

use one of these methods.[17] The methods sponsors use are important because they can affect the amounts that the Government ultimately pays sponsors for providing the benefit. If a reasonable method is not used, sponsors may allocate rebates strategically across plans to increase the payments they receive from the Government.

Related Work

A 2010 OIG report found vulnerabilities in CMS's controls to detect inaccuracies in sponsors' rebate reports.[18] Specifically, the report found that CMS's current controls to ensure the completeness and accuracy of rebate reporting may not find all potential inaccuracies that need to be followed up. It further noted that if rebates are understated and CMS's controls fail to detect the understatement, the sponsor could receive a larger yearend payment from CMS than the amount to which it was entitled. To address this, OIG recommended that CMS strengthen controls to ensure completeness and accuracy of rebate data before reconciliation.

A 2008 report by the Government Accountability Office (GAO) examined how CMS ensures the reliability of the data in sponsors' rebate reports.[19] GAO found that CMS conducted some checks of the reported price concessions data prior to reconciliation to identify outliers and questionable data. GAO also found that CMS had begun fewer than half of the required financial audits intended to evaluate the validity and accuracy of the price concessions data. In addition, GAO found that the variation in defining and reporting price concessions data may create oversight challenges.

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[17] The 2009 guidance states, for example, that allocating rebates based on each plan's use of or total spending for each drug is reasonable. CMS, *Final Medicare Part D DIR Reporting Requirements for 2009 Payment Reconciliation*, June 10, 2010, pp. 13–14. CMS did not provide examples of reasonable allocation methods in its guidance for reporting 2008 rebates.

[18] OIG, *Medicare Part D – Prescription Drug Event Reconciliation Process* (A-18-08-30102), June 2010, pp. 3–4 and 13.

[19] GAO, *Medicare Part D Prescription Drug Coverage: Federal Oversight of Reported Price Concessions Data*, GAO-08-1074R, September 2008, p. 4.

METHODOLOGY

This study focuses on the rebates received by PDPs and MA-PD plans for the 2008 plan year. It is based on data from five sources: (1) all Part D sponsors' rebate reports for 2008, (2) Prescription Drug Event (PDE) data for 2008, (3) all sponsors' bids for 2008, (4) contracts from six selected sponsors, and (5) structured interviews with these six sponsors.

Review of Rebate Reports

To determine the extent to which all Part D sponsors received manufacturer rebates, we reviewed the rebate reports that all sponsors submitted to CMS for 2008. As mentioned earlier, these reports are known as the DIR Reports for Payment Reconciliation. We downloaded these reports from CMS's Health Plan Management System. We included all of the 2008 reports that sponsors submitted as of September 1, 2009.[20]

We analyzed these rebate reports to determine the total amount of rebates that all sponsors reported receiving in 2008. We also determined the amount of these rebates that were retained by PBMs as part of their compensation from sponsors and the total amount of other price concessions that sponsors reported receiving in 2008. We further analyzed the reports to assess the percentage of sponsors that provided rebates to beneficiaries at the point of sale.

To compare the rebates across sponsors, we calculated the per beneficiary per month amount of rebates that each sponsor received. To accomplish this, we obtained from CMS's Health Plan Management System the number of beneficiaries enrolled in each plan for each month in 2008.[21] We used this information to calculate each beneficiary's total enrollment months and aggregated these data for all plans offered by each sponsor.[22] We then divided each sponsor's total rebates by its total enrollment months. We also compared the average per beneficiary per month rebate amount for sponsors with high, medium, and low

[20] We excluded Employer Group Waiver Plans from our analysis. CMS pays sponsors for these plans differently, and as a result, the rebates sponsors receive are not shared with the Government and with beneficiaries in the same manner as described in this report.

[21] CMS Health Plan Management System, *Enrollment Report by Plan*, 2008.

[22] For example, one beneficiary enrolled for the entire year represented 12 enrollment months.

enrollment. We considered sponsors with 500,000 or more beneficiaries to have high enrollment, between 50,000 and 500,000 beneficiaries to have medium enrollment, and 50,000 or less to have low enrollment.

Analysis of Prescription Drug Event Data

Sponsors must submit a PDE record for each drug dispensed under Part D. We used the PDE data to determine total Part D gross drug costs.[23] We determined these costs for all Part D drugs dispensed in 2008 based on three fields in the PDE data: ingredient cost, dispensing fee, and sales tax. We then calculated the total amount of rebates reported by sponsors as a percentage of total Part D gross drug costs.

We also used the PDE data to determine the total amount of rebates sponsors provided to beneficiaries at the point of sale in 2008. Sponsors must indicate whether they provided point-of-sale rebates in their rebate reports; however, the actual dollar amounts of these rebates are contained in the PDE data.

Review of Bids

We compared sponsors' bids to their rebate reports for 2008. For each plan, we compared the amount of rebates and other price concessions included in the bid to the actual amount of rebates and other price concessions reported in the rebate report on a per member per month basis.[24] If a sponsor reported fewer rebates in its bids than it actually received, then beneficiaries' premiums were higher than they otherwise would have been.

Review of Contracts

We selected a purposive sample of six Part D sponsors to review in more depth. We selected these six sponsors based on the number of beneficiaries enrolled in their plans and the PBMs they contracted with to get a variety of sponsors and PBMs for our review. These six sponsors represented more than 25 percent of all Part D beneficiaries in 2008.

For each of these 6 sponsors, we selected a purposive sample of 10 contracts that the sponsor or its PBM had with a drug manufacturer. To select these contracts, we first requested a list from each sponsor of

[23] Total gross drug costs are the total amount paid for Part D drugs before rebates are taken into account.

[24] We excluded the 16 plans that provided rebates to beneficiaries at the point of sale because CMS instructed sponsors to report these rebates in their bids differently from other rebates.

all of the contracts it or its PBM had with drug manufacturers for rebates in 2008. In total, the 6 sponsors or their PBMs had 531 contracts with manufacturers. From these lists, we selected 10 contracts from each sponsor based on the manufacturer and the total dollar amount of rebates associated with the contract. We reviewed these contracts to determine the types of rebates sponsors received from manufacturers and the specific terms and conditions of the rebates.

We also requested and reviewed all of the contracts that the six sponsors had with PBMs in 2008. In total, the six sponsors held nine contracts with PBMs. We reviewed these contracts to determine the nature of the contractual relationships between the sponsors and their PBMs.

Structured Interviews

We conducted structured in-person and telephone interviews with officials from each of the six sponsors to gain a better understanding of their rebates and contractual relationships with PBMs. If the sponsor contracted with a PBM to negotiate rebates, we requested that representatives from the PBM also be included in the interview. In some cases, the representatives from the PBMs requested that we speak to them without the sponsors present because they considered the information confidential.

Our questions to sponsors focused on what types of rebates the sponsors received, how they negotiated these rebates, and how they reported rebates to CMS in their bids and rebate reports. We also asked how they contracted with PBMs and how they ensured that the information they received from their PBMs about rebates was accurate. For some questions, such as how rebates were negotiated, the PBMs answered on behalf of the sponsors. Our questions focused on the 2008 plan year. We conducted these interviews between December 2008 and April 2009.

Limitations

We determined the amount of rebates that sponsors received for plan year 2008 based on the rebate reports. The information in these reports was provided by sponsors, and we did not independently verify these data.

In addition, the information from the six sponsors that we reviewed in greater depth is not generalizable to all sponsors. Lastly, because of the proprietary nature of the data on rebates, this report presents general information and does not include specifics about the rebate amounts and rebate agreements.

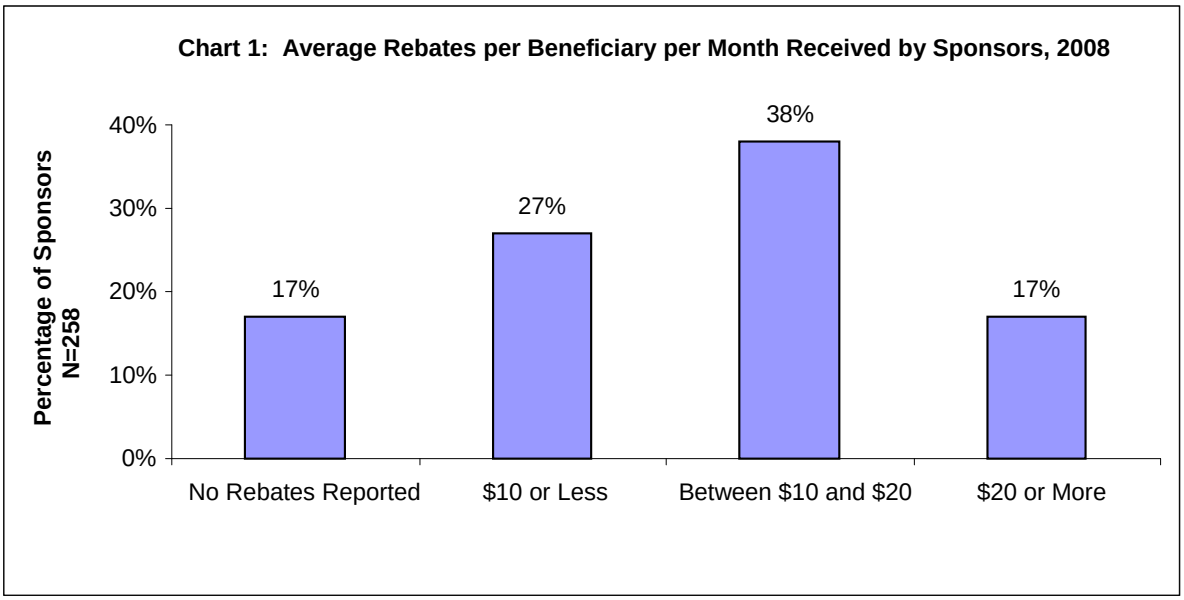
Standards

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.

Medicare Part D sponsors reported receiving $6.5 billion in drug manufacturer rebates in 2008

For 2008, Part D sponsors reported receiving $6.5 billion in manufacturer rebates for Part D drugs. On average, this equaled $275 per beneficiary, or about $7 per drug dispensed in 2008. These rebates were approximately 10 percent of total gross Part D drug costs, which were $63 billion in 2008.[25]

As shown in Chart 1, sponsors reported receiving varying amounts of rebates.[26] Most commonly, sponsors reported receiving between $10 and $20 of rebates per beneficiary per month. The sponsor with the highest amount of rebates reported an average of $75 per beneficiary per month. Interestingly, 17 percent of sponsors reported receiving no rebates at all. These sponsors typically had plans with very low enrollment, representing less than 1 percent of all beneficiaries enrolled in Part D.



Source: OIG analysis of sponsors' rebate reports, 2010.
Note: Totals do not sum to 100 percent because of rounding.

[25] Total gross drug costs are the total amount paid for Part D drugs before rebates are taken into account.

[26] Sponsors reported to CMS the aggregate amount of rebates they received. To compare these amounts across sponsors, we calculated each sponsor's average per beneficiary per month rebate amounts.

Sponsors with large numbers of enrolled beneficiaries typically reported receiving larger rebates per beneficiary per month than sponsors with fewer enrolled beneficiaries. As shown in Table 1, sponsors with high enrollment received an average rebate of almost $25 per beneficiary per month, whereas sponsors with low enrollment received an average rebate of about $11 per beneficiary per month.

Table 1: Rebates Received by Sponsors, 2008

Beneficiary Enrollment in Sponsors' Plans	Number of Sponsors	Percentage of Beneficiaries	Average Rebates per Beneficiary per Month
High enrollment	8	72%	$25
Medium enrollment	27	20%	$15
Low enrollment	223	8%	$11

Source: OIG analysis of sponsors' rebate reports, 2010.

Some sponsors reported large differences in rebates across their plans

The way sponsors allocate rebates across plans is important because it can affect the amount that sponsors owe to or receive from the Government during reconciliation. CMS does not require sponsors to allocate rebates using any particular method.

Specifically, 40 of the 258 sponsors reported receiving rebates that varied more than $25 per beneficiary per month across plans.[27] In fact, one sponsor reported rebates that were $6 per beneficiary per month in one of its plans and $172 per beneficiary per month in another of its plans. The difference across plans may be because of differences in the characteristics of the plans' beneficiaries and their drug use. However, these differences may also indicate that sponsors are inappropriately allocating rebates across their plans to optimize reconciliation payments.

[27] The remaining sponsors had differences that were less than $25.

Sponsors reported that PBMs retained less than 1 percent of all rebates

PBMs may retain a portion of the rebates they negotiate as part of their compensation from sponsors. Sponsors are required to report these rebates in their rebate reports. In 2008, sponsors reported that PBMs retained a total of $24 million, which is less than 1 percent of all rebates. Overall, 39 percent of sponsors reported that their PBMs retained a portion of the rebates for at least one of their plans. The remaining 61 percent of sponsors reported that their PBMs did not retain rebates.

Rebates accounted for 98 percent of all price concessions reported by sponsors

Rebates accounted for almost all of the price concessions that sponsors reported to CMS in 2008. The other types of price concessions amounted to a net total of $142 million. About half ($70 million) of these payments resulted from an arrangement in which a sponsor shared the financial risk with another party involved in the administration or delivery of the Part D benefit, such as a pharmacy. The remaining payments came from other sources, such as discounts from pharmacies for prompt reimbursement or legal settlements.

Sponsors commonly underestimated rebates in their bids, which led to higher beneficiary premiums

Most sponsors did not pass the full amount of manufacturer rebates on to beneficiaries in 2008. Sponsors pass rebates on to beneficiaries in two ways. Sponsors must include an estimate in their bids of the rebates they expect to receive for the plan year. These estimates lower the premiums that beneficiaries pay for drug coverage. Alternatively, sponsors can pass the rebates directly on to beneficiaries at the point of sale.

Sponsors underestimated rebates in 69 percent of their bids, which led to higher premiums for beneficiaries in these plans

Sponsors underestimated rebates in 69 percent of their bids for plan year 2008. When sponsors underestimate rebates in their bids, beneficiary premiums are higher than they otherwise would be. As a result, both the Government and beneficiaries overpay for the benefit. Although the Government recoups some of the overpayments during payment reconciliation, beneficiaries do not recoup any of the money that they paid in higher premiums.

As shown in Table 2, 78 percent of all Part D beneficiaries were enrolled in plans that underestimated the amount of rebates they received. On

average, the sponsors received rebates of $7 per beneficiary per month more than the amounts in their bids.[28] These amounts ranged from less than $1 to $145 per beneficiary per month.

Table 2: Amount of Rebates Sponsors Underestimated in Their Part D Bids, 2008

Underestimated Rebates per Beneficiary per Month	Percentage of Part D Bids	Percentage of Part D Beneficiaries
$10 and over	15%	10%
$5 to less than $10	23%	25%
$1 to less than $5	26%	37%
Less than $1	6%	7%
Totals*	**69%**	**78%**

Source: OIG analysis of sponsors' 2008 bids and rebate reports, 2010.

*Sum of row percentages for each column do not equal totals because of rounding.

In contrast, for 29 percent of bids, sponsors overestimated the rebates. In these cases, the beneficiary premiums were lower than they would have been. On average, the sponsors received rebates of $5 per beneficiary per month less than the amounts in their bids. These amounts ranged from less than $1 to $59 per beneficiary per month. About 2 percent of bids were accurate.

The amounts of rebates included in bids may have been inaccurate because rebates are affected by many factors, such as beneficiary enrollment and drug utilization patterns. Because these factors are often difficult to predict, CMS officials noted that sponsors' estimates of rebates in their bids are not expected to exactly match the rebates they ultimately receive. It is also possible, however, that some sponsors may deliberately underestimate their rebates to increase profits.

Very few sponsors provided rebates at the point of sale

Sponsors may pass rebates on to beneficiaries at the point of sale to reduce beneficiaries' drug costs and copayments. Sponsors did not

[28] Although we cannot determine the exact amount by which this increased beneficiary premiums, the Government provides sponsors with a subsidy equal to approximately 75 percent of the cost of the average bid. Beneficiaries cover the remaining portion of the average bid with their monthly premiums.

commonly pass rebates on to beneficiaries at the point of sale in 2008. Of the 258 sponsors, 4 offered a total of 16 plans that provided rebates to beneficiaries at the point of sale. These rebates amounted to about $8 million and fewer than 1 percent of all Part D beneficiaries were enrolled in these plans.

Selected sponsors received rebates when they encouraged beneficiaries to use certain drugs

Drug manufacturers provide rebates to encourage beneficiaries to use certain drugs over others. The six sponsors we reviewed received two distinct types of rebates: formulary rebates and market-share rebates. Formulary rebates were provided when sponsors' formularies encouraged beneficiaries to use certain drugs over others, whereas market-share rebates were based on the total number of the rebated drugs that beneficiaries used compared to the total number of other drugs used.

In the contracts we reviewed, most of the rebates that the selected sponsors received were based on a fixed percentage of wholesale acquisition cost (WAC).[29] Sponsors received these rebates based on the number of units of the rebated drug dispensed to beneficiaries enrolled in their plans. Sponsors received these rebates even when beneficiaries were responsible for the full cost of the drugs, such as when they were in the coverage gap.[30] In addition, all of the rebates in these contracts were for brand-name drugs.

All six selected sponsors received formulary rebates

All six sponsors received rebates when their formularies and benefit designs encouraged beneficiaries to use certain drugs over others. These types of rebates, commonly known as formulary, or base, rebates required sponsors to include the rebated drugs on their formularies. In the contracts we reviewed, these rebates ranged from 0.5 percent to 75 percent of WAC.

The six sponsors each received rebates based on the placement of the rebated drugs on their formularies. The formularies generally had at

[29] WAC is the manufacturer's list price for the drug for wholesalers or direct purchasers in the United States and does not include discounts, rebates, or other reductions in price. 42 U.S.C. § 1395w-3a(6)(B).

[30] The coverage gap is the phase of the benefit between initial coverage and catastrophic coverage when most beneficiaries must pay the full cost of the drugs.

least three tiers: one for generic drugs, one for preferred brand-name drugs, and one for nonpreferred brand-name drugs. Beneficiaries paid a different copayment for drugs on each tier. For example, in one plan, beneficiaries had a $5 copayment for generic drugs, a $25 copayment for preferred brand-name drugs, and a $60 copayment for nonpreferred brand-name drugs. All six sponsors received rebates for including the drugs on the brand-name preferred tiers.

Sponsors also often received rebates when they discouraged the use of competitors' drugs. As one sponsor noted, "manufacturers pay more for less competition." For example, several rebate agreements specified that a competitor's drug must have a higher copayment than that of the rebated drug. Other agreements required the sponsor to exclude a competitor's drugs from its formulary altogether. Rebates were often larger when fewer competitors' drugs were given preference on the formulary. For example, one sponsor received a 35-percent rebate when the drug was one of two preferred drugs in its class, but a 40-percent rebate when the drug was the only preferred drug in its class on the formulary.

The rebates were also dependent on other aspects of their benefit design. As noted earlier, sponsors can institute utilization management tools, such as requiring a beneficiary to seek prior authorization before covering certain drugs. Sponsors often received rebates under the condition that the rebated drug was not subject to any utilization management tools.

Finally, five sponsors received higher formulary rebates for beneficiaries eligible for the low-income subsidy than for other Part D beneficiaries. For example, one sponsor received a 20-percent rebate for drugs dispensed to low-income subsidy beneficiaries, compared to a 10-percent rebate for the same drug dispensed to other Part D beneficiaries. Manufacturers may have provided higher rebates for low-income subsidy beneficiaries as an incentive to sponsors to move these beneficiaries to the rebated drugs. It may be more difficult for sponsors to move these beneficiaries because they are not subject to the same cost-sharing requirements as other Part D beneficiaries and therefore do not have the same incentives to select preferred drugs. For example, in 2008, low-income subsidy beneficiaries paid, at most, a $5.60 copayment for brand-name drugs and a $2.25 copayment for generic drugs. They did not have a copayment differential between preferred and nonpreferred brand-name drugs.

Five of the six selected sponsors also received market-share rebates

Sponsors received market-share rebates, which were based on the total number of the rebated drugs that beneficiaries used compared to the total number of other drugs used. Sponsors generally received these rebates in addition to formulary rebates. In the contracts we reviewed, market-share rebates ranged from 0.5 percent to 10 percent of WAC.

The specifics of how market-share rebates were calculated varied among sponsors; however, market-share rebates were generally based on the performance of sponsors or PBMs. This performance was determined by comparing utilization of the rebated drugs to other measures, such as national averages. For example, one sponsor received a market-share rebate when the use of a rebated drug was 4 percent higher than the national average for that drug.

Four of the selected sponsors report receiving minimal rebates for drugs in the six protected classes

Sponsors are required to include on each plan's formulary "all or substantially all" of the drugs in six categories. These categories are often referred to as the six protected classes and include immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes. Four of the six selected sponsors raised concerns that they received either no or minimal rebates for the drugs in these six classes.[31] For example, one sponsor explained that there is little incentive for drug manufacturers to offer rebates for these six classes of drugs because they do not need to compete for formulary placement. That sponsor further stated that "If [a rebate] is provided, it's probably at a lower percentage than [the rebate for the drugs] that had some competition."

As mentioned earlier, for plan year 2011, CMS is responsible for reassessing the drugs that sponsors will be required to include on their formularies. Because sponsors report receiving fewer rebates for such drugs, any changes CMS makes could affect the overall cost of the Part D program.

[31] The remaining two sponsors did not comment on this issue.

Selected sponsors had complex contractual relationships with PBMs that sometimes lacked transparency

CMS holds sponsors ultimately responsible for accurately reporting rebates and for ensuring that their PBMs comply with CMS requirements.[32] The six selected sponsors commonly had complex relationships with their PBMs, and in some cases, these relationships lacked transparency. This lack of transparency raises concerns that sponsors may not always have enough information to oversee the services and information provided by PBMs.

Contractual relationships between selected sponsors and PBMs were varied and complex

All of the six selected sponsors had contracts with at least one PBM to negotiate with drug manufacturers for rebates for their plans. In these cases, the PBMs, not the sponsors, entered into contracts with the manufacturers and collected the rebates. In addition, all six sponsors relied on their PBMs to provide the aggregate data on rebates and other price concessions that sponsors are required to report to CMS.

Sponsors had a variety of complex contractual relationships with the PBMs. Two sponsors contracted with more than one PBM. In addition, some PBMs were owned by the same parent company as the sponsor. Some PBMs were also sponsors themselves and offered their own Part D plans. For example, one sponsor owned a PBM that served some of its own Part D plans as well as other sponsors' plans. This sponsor also contracted with another PBM that had its own Part D plan.

There was limited transparency between the selected sponsors and their PBMs related to rebates

Five sponsors had limited information about the rebate contracts and the rebate amounts negotiated by their PBMs. One PBM reported that it does not share the manufacturer rebate contracts with its sponsors because they contain confidential information and there is a chance that the sponsor may one day become a PBM itself. Another PBM specifically stated that the sponsor would "not be permitted to copy or retain" any portion of the contract. As a result of these practices, most

[32] CMS's *Prescription Drug Benefit Manual* states that sponsors are ultimately responsible for complying with all statutory, regulatory, and other requirements. They must also ensure that their subcontractors, including their PBMs, are in compliance with all applicable laws, rules, and regulations with respect to any Part D delegated responsibilities. CMS, *Prescription Drug Benefit Manual,* ch. 9, § 40.1.

of the selected sponsors were unaware of all of the contract terms that determine the rebates they receive from drug manufacturers.

Several of the sponsors also had limited information about the rebate amounts they actually received for each drug. As one sponsor explained, its PBM provided aggregate information for all the rebates associated with each Part D plan, rather than by drug name. As a result, this sponsor did not know the amount of rebates it received for each drug.

Several sponsors and PBMs further noted that the PBM industry is extremely competitive and, as a result, information about a PBM's business practices, including the rebate contracts and the negotiated rebate amounts, is highly confidential. In fact, the PBMs in our study were, in some cases, unwilling to discuss details about their business practices in front of the sponsor.

Selected sponsors relied primarily on audits to verify the rebate amounts, and these audits were sometimes limited

The selected sponsors relied primarily on audits to verify that they received the appropriate amount of rebates and that the rebate data they reported to CMS were accurate.[33] In some cases, the scope of what the sponsor could audit was restricted. According to one sponsor's contract with its PBM, the sponsor could audit a limited number of its rebate agreements for the two quarters immediately preceding the audit. However, the contract also stated that the manufacturer had the right to deny the sponsor access to rebate agreements requested for the audit. Another PBM contract stated that the sponsor could review only a sample of rebate agreements. A third sponsor's contract with its PBM stated that the sponsor had the right to audit only certain parts of the rebate agreements. In addition, two sponsors were required to use a third-party auditing firm to perform these audits.

Selected sponsors reported that their PBMs collected fees from drug manufacturers that were not always passed on to the Part D program

Five of the six selected sponsors reported that their PBMs received fees from drug manufacturers, in addition to the fees that sponsors paid PBMs for negotiating rebates.[34] These fees were structured like rebates

[33] Several sponsors also explained that they conducted a broad-level data analysis to roughly check the amount of rebates that they should have received.

[34] The sixth sponsor reported that its PBM did not receive these fees.

in that they were generally based on a fixed percentage of WAC. According to the contracts we reviewed, these fees were for services that the PBM provided to the manufacturers, such as negotiating rebates, calculating rebate amounts, and distributing rebates to sponsors.

The PBMs handled these fees somewhat differently. For example, two of the PBMs considered these fees to be rebates and provided them to the sponsors. As a result, these sponsors reported them to CMS and passed them on to the Government, thereby reducing the overall cost of the Part D program.

In the other three cases, the PBMs considered these fees to be for services they provided to the manufacturers and therefore they did not pass them on to the sponsors. As a result, the sponsors did not report the fees to CMS and therefore they were not passed on to the program. Specifically, the PBMs considered these fees to be bona fide service fees, which CMS does not consider price concessions if they are at fair market value. The contracts we reviewed between the sponsors and the PBMs had only limited information about these fees. Because sponsors may not always be able to verify whether these fees should be considered rebates or bona fide service fees, they may be inaccurately reporting this information to CMS.

RECOMMENDATIONS

Our report found that drug manufacturer rebates totaled $6.5 billion in 2008, representing about 10 percent of Part D drug costs. Because of the size of these rebates, it is vital that rebates be reported accurately and that the Government and beneficiaries receive the full benefit of these rebates.

We identified several concerns about these rebates. We found that some sponsors reported large differences in rebates across their plans. We further found that most beneficiaries did not receive the full benefit of rebates. Notably, sponsors underestimated rebates in 69 percent of their bids, resulting in beneficiary premiums that were higher than they otherwise would have been. We also found that contractual relationships between selected sponsors and their PBMs sometimes lacked transparency and that sponsors sometimes lacked the ability to oversee the services and information provided by PBMs. Finally, we found that some sponsors passed the fees that their PBMs received from manufacturers on to the program, while others did not.

Based on these findings, we recommend that CMS:

Take steps to ensure that sponsors more accurately include their expected rebates in their bids

Beneficiaries benefit from rebates that are included in the bids; therefore, it is essential that sponsors report all of the rebates they expect to receive. After the close of each plan year, CMS should compare the actual rebates that sponsors reported to the rebates in sponsors' bids. CMS should work with the sponsors that have particularly large differences to ensure that these differences do not occur in the future. CMS should also consider targeting these sponsors in its financial audits.

Require sponsors to use methods CMS deems reasonable to allocate rebates across plans

The methods sponsors use to allocate rebates across plans may affect the amount that the Government pays for the Part D program. In its guidance for reporting 2009 rebates, CMS provides a list of allocation methods it considers reasonable, such as allocating rebates based on drug utilization or spending. CMS should make any necessary changes to this list. It should require sponsors to either use one of the methods it determines to be reasonable or submit documentation proving that an alternative method is reasonable.

Ensure that sponsors have sufficient audit rights and access to rebate information

Sponsors are ultimately responsible for accurately reporting their rebates to CMS. CMS should ensure that sponsors have sufficient information to accurately report rebates. To do this, CMS could require sponsors to have stronger provisions in their contracts related to their audit rights and access to rebate information. CMS could also provide more detailed guidance to sponsors about how they should monitor PBM rebate information.

Ensure that sponsors appropriately report the fees that PBMs collect from manufacturers

CMS should work with sponsors to gain a better understanding of the circumstances under which some sponsors are reporting these fees as rebates and others are not. CMS should clarify when these fees should be reported as rebates. In addition, beginning for plan year 2009, CMS required sponsors to report all payments that meet the definition of "bona fide service fees," including those that the PBM retains and does not share with the sponsor. CMS should use this information to monitor the fees and ensure that they were reported appropriately. It should also use the information—and perhaps target certain sponsors to audit—to assess whether these fees should actually be considered rebates and therefore should be taken into account in reconciliation.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with one of our recommendations in the draft report and partially concurred with another. CMS did not concur with the remaining two recommendations.

CMS concurred with our first recommendation, to ensure that sponsors more accurately include rebates in their bids. CMS stated that it will consider adding to its bid review a comparison of the rebates sponsors actually receive and include in their rebate reports to the rebates they include in their bids. CMS further stated that it is more effective to review rebate data before the bids are approved than to audit the data after bids have been approved, noting that this helps ensure that beneficiaries and the Government receive the benefit of the rebates in beneficiary premiums and the prospective Part D payments.

CMS did not concur with our second recommendation, to require sponsors to use certain methods to allocate rebates across plans. CMS

stated that it currently requires sponsors to use a reasonable allocation methodology that reflects differences in utilization and spending. CMS stated that sponsors should be allowed to use a methodology other than those enumerated by CMS. It noted that it will continue to collect and review information from sponsors regarding their methods for reporting rebates across plans and will consider whether it is appropriate to provide additional guidance.

Our findings show that sponsors may be inappropriately allocating rebates across plans. Because this may result in a loss to the Government, we continue to recommend that CMS require sponsors to use allocation methods it deems reasonable. This would enable CMS to better monitor how sponsors are reporting rebates and would thereby enable CMS to better safeguard the Part D program. In response to CMS's comments, in our final report we reworded our recommendation and added a sentence recommending that if sponsors choose an alternative method, they must submit documentation proving that it is reasonable. We believe that this would allow sponsors some flexibility but at the same time enable CMS to ensure that the methods are in fact reasonable.

CMS did not concur with our third recommendation, to require sponsors to have sufficient audit rights and access to rebate information. CMS stated that it has taken steps to promote transparency and to make sponsors responsible for the accuracy of the rebate information they report to CMS. It further noted that it believes the current regulatory framework strikes the appropriate balance to encourage sponsors to negotiate sufficient disclosure of information from their PBMs, while recognizing the PBMs' view that certain information is highly confidential. In addition, CMS commented that it believes the Government's access to rebate information is more crucial to the integrity of the Part D program and that it has already imposed requirements on sponsors to address the Government's need for transparency.

We are aware of the current regulatory framework and the importance of balancing the interests of sponsors and PBMs. However, this report shows that some Part D sponsors have limited rights to audit their PBMs and limited access to information about their rebates. Without adequate information, sponsors cannot fulfill their responsibility to ensure the accuracy of the rebate information they report to CMS. In response to CMS's comments, we modified our recommendation and

offered two ways for CMS to ensure that sponsors have sufficient audit rights and access to rebate information. Specifically, CMS could require sponsors to have stronger provisions in their contracts related to their audit rights and access to rebate information. CMS could also provide more detailed guidance to sponsors about how they should monitor PBM rebate information. Finally, while we agree with CMS that Government access to rebate information is crucial to the integrity of the program, we stress that sponsors' having sufficient audit rights and access to rebate information is also essential to safeguarding the program.

CMS partially concurred with our fourth recommendation, to ensure that sponsors appropriately report the fees that PBMs collect from manufacturers. CMS noted that it does not concur that more specificity is required in the definition of "bona fide service fees." However, CMS stated that it plans to continue to collect information from sponsors regarding the bona fide service fees received by their PBMs and that it uses this information to ensure that fees are appropriately reported to CMS. CMS stated that this information will also be used to provide additional guidance to Part D sponsors regarding bona fide service fees as appropriate. However, this report shows that sponsors are reporting these fees differently. While CMS may not need to change the definition of "bona fide service fees," it may need to provide additional guidance or clarification to sponsors about when sponsors need to report these fees as rebates, which thereby reduce the amount the Government pays for the program.

We also made technical corrections to the report based on CMS's comments. For the full text of CMS's comments, see Appendix A.

Centers for Medicare & Medicaid Services Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: DEC 1 6 2010

TO: Daniel R. Levinson
Inspector General

FROM: Donald M. Berwick, MD
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Concerns with Rebates in the Medicare Part D Program (OEI-02-08-00050)

Thank you for the opportunity to review and comment on this OIG draft report, which evaluates rebates in the Medicare Part D Program. The objective of the study was to review the rebates received by Part D sponsors and reported to the Centers for Medicare & Medicaid Services (CMS) in order to determine the following:

- The extent to which all Part D sponsors received rebates in 2008;
- The extent to which all Part D sponsors passed rebates on to beneficiaries;
- The nature of the rebates received by selected sponsors; and
- The nature of selected sponsors' contractual relationships with pharmacy benefit managers (PBMs).

The OIG made several recommendations to ensure that rebates are reported accurately such that the Government and beneficiaries receive the full benefit of these rebates. Currently, CMS conducts several reviews of the rebate and other price concessions data reported by Part D sponsors to ensure that these data are reported accurately to CMS. Specifically, CMS evaluates the rebates amounts projected in the Part D bids, conducts reasonableness reviews on the direct and indirect remuneration (DIR) data prior to inclusion in Part D payment reconciliation, and validates the DIR data during the Part D financial audits. However, given the impact of these data on the costs incurred by beneficiaries and the Government, CMS understands the OIG's concerns. We look forward to continuing to work with the OIG to strengthen the Medicare Part D Program. Below is CMS' response to the OIG's recommendations.

OIG Recommendation

CMS Should Take Steps to Ensure That Sponsors More Accurately Include Their Expected Rebates in Their Bids.

CMS Response

CMS concurs with this recommendation. When developing the Part D bids, Part D sponsors project data from a previous year (the base period) to the applicable contract year as appropriate. During the bid reviews, the base period or actual experience that is reported in the bid is reviewed and reconciled to the PDE information submitted by the Plan sponsor for payment. Currently, CMS reviews the projected rebates and the relationship between the projected rebates and those reported in the bid for the base period to ensure that the development is reasonable and substantiated by historical and projected experience provided by the Plan sponsor and its PBM.

It is difficult to reconcile the base period rebates to the CMS direct and indirect remuneration (DIR) report because of timing issues. Specifically, the "actual" value of the base period rebates is not known by the Plan sponsor at bid preparation because of the lag between the time the rebate is incurred and ultimately paid by the manufacturer. However, CMS will consider adding a comparison of the rebates actually received and reported on the DIR reports and the rebates reported in the bids to the bid reviews.

When developing their Part D bids, Part D sponsors are required to include their best *estimate* of the rebates they expect to receive during the contract year. Given the variability in plan enrollments, drug utilization, and rebate contracts, it can be difficult for Part D sponsors to accurately estimate their rebates in the Part D bids. In addition, overestimating rebates in the Part D bids can result in a Part D sponsor receiving less revenue than necessary to provide the Part D benefit, putting the Part D sponsor at risk. As a result, Part D sponsors are generally conservative in their rebate estimates, underestimating their Part D rebates. However, we believe that the competitive nature of the Part D program provides a disincentive for Part D sponsors to significantly underestimate their rebates in the Part D bids as this would increase their beneficiary premiums and make their plans less competitive.

Once CMS approves the Part D bids, they cannot be changed. Therefore, any findings from audits conducted after a bid has been approved could not be used to change the approved bid or the beneficiary premiums and prospective federal payments determined based upon the approved bid. As a result, CMS believes that it is more effective to review rebate data prior to the bid being approved rather than auditing the data after bids have been approved. This helps to ensure that beneficiaries and the Government receive the benefit of rebates in beneficiary premiums and the prospective Part D payments.

OIG Recommendation

CMS Should Require Sponsors to Use Certain Methods to Allocate Rebates Across Plans

CMS Response

CMS does not concur with this recommendation. We agree that the allocation of rebates across Part D plans may affect the payments made by the Government. For this reason, CMS currently requires Part D sponsors to use a reasonable allocation methodology that reflects differences in utilization and spending on rebate-eligible drugs across the sponsor's Part D plans. However, it is

often appropriate for Part D sponsors to report varying levels of rebates across their Part D plans due to differences in formulary, plan design, and drug utilization. CMS therefore disagrees with OIG's recommendation that sponsors be prohibited from using a reasonable allocation methodology other than those enumerated by CMS. CMS will continue to collect and review information from Part D sponsors regarding their methods for reporting rebates across Part D plans. In addition, we will continue to assess the allocation methods reported by Part D sponsors during our reviews of the DIR data to determine whether each Part D sponsor is using a reasonable method to allocate their rebates. As we learn more from Part D sponsors, we will consider whether it is appropriate to provide additional guidance regarding the methods that should be used to reasonably allocate rebates across their Part D plans.

OIG Recommendation

CMS Should Require Sponsors to Have Sufficient Audit Rights and Access to Rebate Information

CMS Response

CMS does not concur with this recommendation. CMS is aware of the value of rebate information to the administration of the Part D program, and recommends Part D sponsors audit rebate information of their contracting PBM in order to fulfill the sponsor's responsibility to ensure its accuracy. In addition, CMS has taken steps within the framework of the program to promote the transparency of such information to the Government and to make Part D sponsors responsible for the accuracy of rebate information they report to CMS.

CMS frequently reminds Part D sponsors that, pursuant to 42 C.F.R. §423.505(i), it holds each of them accountable for their compliance with all Part D program requirements, regardless of whether they have delegated responsibility for the performance of certain requirements to contracted first tier or downstream entities.

Sponsors are also required, pursuant to 42 C.F.R. §423.505(i)(4)(iii), to include provisions in their contracts with first tier and downstream entities that specify that they can monitor the performance of the delegated entities on an ongoing basis. Under Chapter 9 of the Prescription Drug Benefit Manual (50.2.6.1.3), CMS informs Part D sponsors they should audit PBM rebate information as part of their responsibility to monitor first tier and downstream entities for waste, fraud and abuse. We believe this regulatory framework strikes the appropriate balance. It encourages contract negotiations between plan sponsors and PBMs that provide for sufficient disclosure to enable plan sponsors to comply with CMS requirements, recognizing that PBMs view certain information as highly confidential because of the extremely competitive nature of the industry.

CMS believes that transparency as it relates to the government's access to rebate information and the right to conduct audits is more crucial to the integrity of the Part D program as the government (not Part D sponsors, as the draft report states on pages ii and 17) is ultimately responsible for oversight of the Part D program. To that end, CMS believes that it has already imposed requirements on Part D sponsors with respect to their contracts with first tier and

downstream entities necessary to address the government's need for transparency. For example, all Part D sponsors are required, pursuant to 42 C.F.R. § 423.505(i)(2)(i), to have provisions in their contracts with entities to which they have delegated Part D functions that require the entities to afford HHS, including CMS and the OIG, access to audit, evaluate, and inspect any information related the sponsor's Part D operations. This includes information concerning rebate arrangements between the sponsor and its PBM. CMS will continue to closely review the contractual arrangements of current sponsors as well as organizations applying for new Part D sponsor contracts to ensure that the government has access to comprehensive information concerning Part D program operations.

OIG Recommendation

CMS Should Ensure That Sponsors Appropriately Report the Fees That PBMs Collect From Manufacturers

CMS Response

CMS partially concurs with this recommendation. Part D sponsors are required to report all amounts received from drug manufacturers (either directly or through their PBM) as direct and indirect remuneration (DIR). This includes the difference between any payment to a Part D sponsor or its PBM from a pharmaceutical manufacturer for bona fide services and the fair market value of those services.

In addition, Part D sponsors are required to report any rebate administration fees received by Part D sponsors or their PBMs that meet the definition of bona fide service fees. However, because fees collected by PBMs that meet the definition of a bona fide service fee do not affect the drug costs incurred by the Part D sponsors, these fees are not reported to CMS as direct and indirect remuneration (DIR) and are not passed on to the Part D program. Rather, the requirement to submit information on bona fide service fees allows Part D sponsors and CMS to ensure that rebate administration fees that exceed fair market value are reported as DIR.

CMS provides a definition of bona fide service fees in the DIR reporting requirements made available to Part D sponsors. This definition in conjunction with the guidance provided in the DIR reporting requirements clearly explains which manufacturer fees must be reported to CMS as DIR. Furthermore, the definition provided is consistent with the definitions utilized in the Medicaid and Medicare Part B programs. Therefore, CMS does not concur with the OIG's recommendation that more specificity is required in the definition of bona fide service fees.

CMS plans to continue collecting information from Part D sponsors regarding the bona fide service fees received by their PBMs. We currently review this information prior to the Part D payment reconciliation to ensure that these fees are appropriately reported to CMS. This information will also be used to provide additional guidance to Part D sponsors regarding bona fide service fees as appropriate.

We appreciate the effort that went into this report. Again, we thank you for the opportunity to review and comment.

ACKNOWLEDGMENTS

This report was prepared under the direction of Jodi Nudelman, Regional Inspector General for Evaluation and Inspections in the New York regional office, and Meridith Seife, Deputy Regional Inspector General.

Miriam Anderson served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the New York regional office who contributed to this report include Jenell Clarke, Levita Lowe, and David Rudich; central office staff who contributed include Kevin Farber and Rita Wurm.

Office of Inspector General

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