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United States Government Accountability Office
Washington, DC 20548

September 30, 2008

The Honorable Henry A. Waxman
Chairman
Committee on Oversight and Government Reform
House of Representatives

Subject: *Medicare Part D Prescription Drug Coverage: Federal Oversight of Reported Price Concessions Data*

Dear Mr. Chairman:

To help Medicare beneficiaries manage the rising cost of prescription drugs, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which established the outpatient prescription drug benefit known as Medicare Part D.[1] The benefit was first available in January 2006, and that year it provided federally subsidized prescription drug coverage for nearly 28 million beneficiaries at a cost of $47.4 billion—almost 12 percent of total Medicare spending. The Centers for Medicare & Medicaid Services (CMS), part of the Department of Health and Human Services (HHS), manages and oversees the Part D program.

Part D sponsors—entities that enter into contracts with Medicare[2]—administer the benefit and compete for beneficiary enrollment. To provide coverage, the sponsors often enter into contractual relationships with pharmacy benefit managers (PBM),[3] drug manufacturers, and retail pharmacies, among others. The Part D program relies on sponsors to generate prescription drug savings, in part through their ability to negotiate price concessions, such as rebates and discounts, with these entities. Sponsors must report the price concession amounts to CMS and pass price concessions on to the program.[4] CMS uses the reported data to calculate final plan payments, so accurate data are necessary to ensure accurate payments. CMS is responsible for ensuring that the reported price concessions data are reliable.

[1]Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071-2152 (inserting a new Part D into title XVIII of the Social Security Act (SSA)).

[2]Part D sponsors are typically private health plans or insurers. In addition to their Medicare business, Part D sponsors typically offer drug coverage in the private insurance market.

[3]Health insurers may contract with PBMs to help manage their prescription drug benefits. PBMs often negotiate drug prices with pharmacies and drug manufacturers on behalf of health plans and, in addition to other administrative, clinical, and cost containment services, process drug claims for the health plans.

[4]*See* SSA sections 1860D-2(d)(2), -15(b)(2) and -15(e)(1)(B) (as added by the MMA) (codified at 42 U.S.C. §§ 1395w-102(d)(2), -115(b)(2), and -115(e)(1)(B)).

We and others have reported challenges to the oversight of federal prescription drug programs that rely on privately reported data, noting significant financial consequences for the federal government resulting from inaccurate reporting.[5] You asked us to provide information on the price concessions data CMS collects. Specifically, we examined how CMS ensured the reliability of the 2006 price concessions data, the most recent complete year of data for which CMS had conducted oversight activities.

To examine CMS's oversight of the reported price concessions data, we reviewed laws, regulations, and guidance related to Part D reporting requirements and CMS's oversight of price concessions data, including audit guidelines and methodologies. We also interviewed CMS officials responsible for collecting and overseeing the data to learn about its purpose and use, oversight activities, and any challenges to the oversight. We interviewed CMS officials from the Center for Drug and Health Plan Choice, who manage Part D data collection efforts and plan payment activities, and from the Office of Financial Management, who manage Medicare's financial audits. Our review focused primarily on the price concessions data contained in the 2006 Direct and Indirect Remuneration (DIR) reports, which were used to determine the final program payment reconciliation. We also examined the management of quarterly reported price concessions data. We conducted this work from April 2008 through September 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

For each Part D program year, CMS requires Part D sponsors to submit two types of reports that reflect price concessions data—an annual DIR report and quarterly reports of drug manufacturer rebates, discounts, and other price concessions data. Many sponsors have multiple contracts with CMS, with each contract offering one or more distinct Part D plans.[6] Sponsors report the annual DIR data by plan and report the quarterly data by sponsor or contract.

Part D Program Year

The Part D program year runs from January 1 through December 31. Part D sponsors submit separate annual bids for each plan in June preceding the program year—therefore bids for program year 2006 were submitted in June 2005. CMS pays sponsors prospectively based on those bids, which include estimated program costs and estimated price concessions the

[5]See GAO, *Prescription Drugs: Oversight of Drug Pricing in Federal Programs*, GAO-07-481T (Washington, D.C.: Feb. 9, 2007). In addition, the HHS Office of Inspector General (HHS-OIG)—responsible for protecting HHS programs against fraud, waste, and abuse—identified oversight of Medicare Part D as its top management and performance challenge for fiscal year (FY) 2007 due to the complex structure and the cost of the program. See *HHS FY 07 Agency Financial Report.: FY 2007 Top Management and Performance Challenges Identified by the Office of the Inspector General (Washington, D.C.: Nov. 15, 2007)*. In this report the HHS-OIG also estimated that Part D sponsors would owe Medicare a net total of $4.4 billion after the 2006 final plan payment adjustments.

[6]Plans offered under the same contract may differ in their benefit design, such as the specific drugs the plans covered and the premiums they charged.

sponsors will receive during the program year. After the close of a program year, CMS reconciles payment disbursements based on actual costs incurred. Actual costs must reflect actual plan enrollment and utilization, and must be net of price concessions reported in the DIR data. The 2006 DIR data were reported to CMS in July 2007 and the reconciliation payments were calculated in September 2007.

Annual DIR Reports for Payment Reconciliation

The DIR reports include aggregate values of the types of price concessions each plan received from any source, such as those received from pharmacies or rebates received from drug manufacturers. Because the DIR reports are used to calculate payments, they are subject to audit and sponsors must attest to their accuracy. CMS is required to conduct financial audits of payment data, including DIR data, for at least one-third of the Part D sponsors each program year.[7] It contracts with external auditors to conduct the audits.

DIR reporting guidance states that any transactions that effectively lower the cost to the plan for purchasing drugs should be reported as price concessions. For example, Part D sponsors typically pay PBMs for the cost of drugs provided to their plan enrollees. PBMs also receive payments from drug manufacturers based on contractual agreements for managing and distributing drug rebates to the sponsors—referred to as rebate administration fees. According to the guidance, any amount of the rebate administration fees that exceeds the fair market value of the service should be reported as price concessions. The guidance does not specifically define the fair market value of these or other types of fees specified in sponsors' or PBMs' contracts. When reporting DIR data, sponsors may also have to consider how to allocate price concessions that apply to both their Part D and other business. DIR reporting guidance does not specify how sponsors should allocate price concessions, but it requires that the sponsors use a reasonable allocation method and maintain documentation to explain and support their allocation methods.[8]

Quarterly Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions Reports

The quarterly price concessions reports include some of the information captured in the DIR reports; however, there are some key differences. The quarterly reports include price concessions received only from drug manufacturers, while the annual DIR reports include price concessions from any source, such as pharmacies. In addition, the quarterly reports include price concessions by drug rather than in aggregate, detailing any manufacturer rebates by drug. They also include detailed descriptions, values, and justifications for nonrebate discounts and other price concessions from drug manufacturers, such as coupons. The quarterly reported data are not used to determine program payments and CMS does not subject these data to financial audit.

[7]SSA section 1860D-12(b)(3)(C) (as added by the MMA) (codified at 42 U.S.C. § 1395w-112(b)(3)(C)); 42 C.F.R. § 423.504(d) (2007).

[8]In addition to CMS's financial audits, the HHS-OIG is examining the documentation used to support DIR and other reported price concessions data. For example, it is initiating audits of reported DIR data and a review of a sponsor's support for its estimates of price concessions included in its bids.

Results in Brief

CMS conducted checks of the reported price concessions data prior to reconciling the 2006 payments to identify certain potential problems, and has initiated about half of its planned financial audits to examine the data in more detail. According to CMS officials, they conducted data checks prior to payment reconciliation to identify potential problems such as outliers and questionable data. Where officials identified problems with the data, they contacted sponsors and resolved most problems before payment reconciliation. CMS officials said they do not expect the data checks to identify all possible problems, but they rely on them as a vital step to ensure a certain level of confidence in the data in the absence of sufficient time to fully review or audit them before payment reconciliation. The officials said that the financial audits, which occur after payment reconciliation, allow them to more fully evaluate the accuracy and validity of the data. CMS intends to complete 169 financial audits of Part D contracts for program year 2006. Officials expect to complete about half of the planned audits by October 2008—within CMS's targeted timeline for conducting all of the audits of 2006 data. According to CMS officials, the remaining audits were delayed due to financial constraints and CMS, therefore, funded the audits from two program year budgets. The officials expected to complete the delayed audits by October 2009 and did not expect that audits of program year 2007 data would be similarly delayed. In addition, officials noted that variation in defining and reporting price concessions data, such as variation in how sponsors allocate manufacturer rebates between their Part D plans and other business, would likely create oversight challenges. We received written comments on a draft of this report from HHS. HHS stated that the draft correctly characterized the financial audit program, but did not adequately emphasize the robustness of CMS's other oversight activities. We revised the draft to reference further detail about CMS's data checks and clarified our characterization of their purpose.

CMS Conducted Data Checks to Identify Certain Potential Problems, Initiated About Half of the Required Audits, and Acknowledged Certain Oversight Challenges

CMS conducted checks of the reported price concessions data prior to reconciling the 2006 payments and will rely on the financial audits begun after the reconciliation to more fully evaluate the accuracy and reliability of the data. Officials acknowledged certain problems inherent in defining and reporting price concessions data that may present challenges for oversight.

Data Checks Conducted Prior to Payment Reconciliation Are Intended to Identify Outliers and Questionable Data

CMS officials stated that they conducted 10 data checks to identify certain potential problems in the 2006 DIR, such as outliers and questionable data, before using the data for payment reconciliation and audit.[9] Officials acknowledged that the checks provided a high-level review, and were not expected to identify all possible problems with reported data. However, CMS officials said they used the data checks because they lacked the time to conduct audits or more detailed analyses before the data were used for payment

[9]In commenting on a draft of this report, HHS provided an updated list that included 12 data checks that CMS intends to use in its review of the 2007 DIR reports (see encl. I, attachment A).

reconciliation.[10] They believed the checks were vital to ensure a certain level of confidence in the quality of data. The 10 data checks included three types of analyses:

- Comparisons of the 2006 DIR data with the estimated price concessions data reported in each plan's program year 2008 bids, which were submitted in June of 2007. CMS officials expected plans' 2006 DIR data to mirror their 2008 bid data because plans were generally required to use their 2006 experience to project costs for 2008.[11]

- Comparisons of the 2006 DIR data with an annual sum of the data from the quarterly reports of manufacturer price concessions. Because the DIR data include price concessions from more sources than the quarterly data, they sought to ensure that the value of the DIR data was the greater of the two.

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- Checks for outliers. For example, among plans with similar characteristics, officials compared plans' reported DIR data in relation to their total drug spending to determine whether any reported DIR seemed particularly high or low.

CMS officials said they followed up with sponsors whose data checks identified problems with the program year 2006 DIR data. Where they found inconsistencies, officials contacted the sponsors to determine whether the inconsistencies could be reasonably explained. In addition, CMS sent warning letters to 22 sponsors that had not submitted DIR reports by the reporting deadline of July 9, 2007, indicating that they should submit their data by July 25, 2007, or they may be subject to potential enforcement actions.[12] Officials told us that most problems were resolved before payment reconciliation through conversations with sponsor representatives. One sponsor that did not submit data by July 25 was reported to CMS auditors for their use in determining the sponsors to target for future audit.[13]

CMS officials stated that the newness of the program and other factors affected the usefulness of the data checks, and they expected that some challenges would diminish as they gain program experience. For example, they stated that the value of the comparison between the 2006 DIR data and the estimated price concessions data from the 2008 bids was limited because the bids were based on only 1 year of actual experience with Part D enrollment and utilization. Officials believed that as sponsors gained Part D program experience, the accuracy of bids and the usefulness of these comparisons could improve. In addition, while the officials said that comparisons of DIR data across like plans may have identified outliers, they noted that differences in reported DIR data may not always indicate problems because they may be attributable to differences in plan design or enrollees' characteristics and drug utilization. Officials believed that as they gained experience reviewing DIR data across multiple plans, their ability to identify possible problems through the data checks would improve. However, CMS officials acknowledged that the data checks

[10]The 2006 DIR data were submitted in July 2007. CMS calculated 2006 payment reconciliation in early September 2007 and sent reports to sponsors in early October 2007 informing them of their adjusted payment.

[11]Bids for a given program year are due to CMS by June of the previous year. When CMS reviewed the 2006 DIR data, the bids for program year 2008 were the most recently available.

[12]The letters pertained to 40 contracts and 175 plans offered by the 22 sponsors.

[13]Although CMS expects to audit at least one-third of the Part D sponsors each program year—auditing all sponsors over a 3-year cycle—it may audit certain sponsors more than once every 3 years if, for example, there are questions about prior data submissions.

would always be limited to identifying certain potential problems or inconsistencies in reported data. For example, CMS officials told us that the comparison of the DIR data with the quarterly manufacturer price concessions data provided only a high-level check for reporting consistency because the two sets of data did not capture the same information.

Audits Are Intended to Evaluate the Reliability of the Price Concessions Data, and About Half of the 2006 Audits Were Delayed

CMS officials stated that they intend to use the financial audits conducted after payment reconciliation to evaluate the accuracy and reliability of the DIR data. According to the 2006 audit plan, financial audits should include reviews of each plan's DIR calculations and price concessions allocation methods, as well as DIR calculations provided to the sponsors by their PBMs. The audit plan specifies that auditors should attempt to determine if PBMs retained any rebates not reported in the DIR data.[14] Auditors must also evaluate a sample of payment and revenue reports and supporting documentation to identify and test any unreported DIR. The audit plan requires auditors to document methodologies and any findings and conclusions for each audit. CMS officials stated that if financial audits identify problems with a sponsor's DIR reports or CMS's payment reconciliation, CMS will recalculate payment reconciliation for that sponsor and target them for future audit. The 2006 audits targeted contracts based on total enrollment and spending, not on suspected problems in reporting financial data, such as the DIR data. Officials told us that future audits would likely target sponsors based on reporting or compliance problems identified in the data checks and previous financial audits.

Officials stated that about half of the 2006 audits were delayed. To fulfill statutory requirements, CMS planned to contract for 169 financial audits of Part D contracts representing plans managed by 97 different sponsors. CMS's target timeline for receiving final results of the financial audits is within 22 months of the end of the program year—which would be October 2008 for the 2006 program year.[15] CMS contracted for 81 of the audits to be completed by October 2008—within the target timeline. According to CMS officials, the remaining audits were delayed due to financial constraints and CMS, therefore, funded the audits from two program year budgets. Officials said they expect to begin the remaining 88 audits of program year 2006 data in October 2008, and expect completed results for those audits by October 2009.[16] (See fig. 1.) CMS officials did not expect that audits of program year 2007 data would be similarly delayed. According to officials, as of July 11, 2008, they had received final results from one program year 2006 audit which found no problems related to the DIR data.

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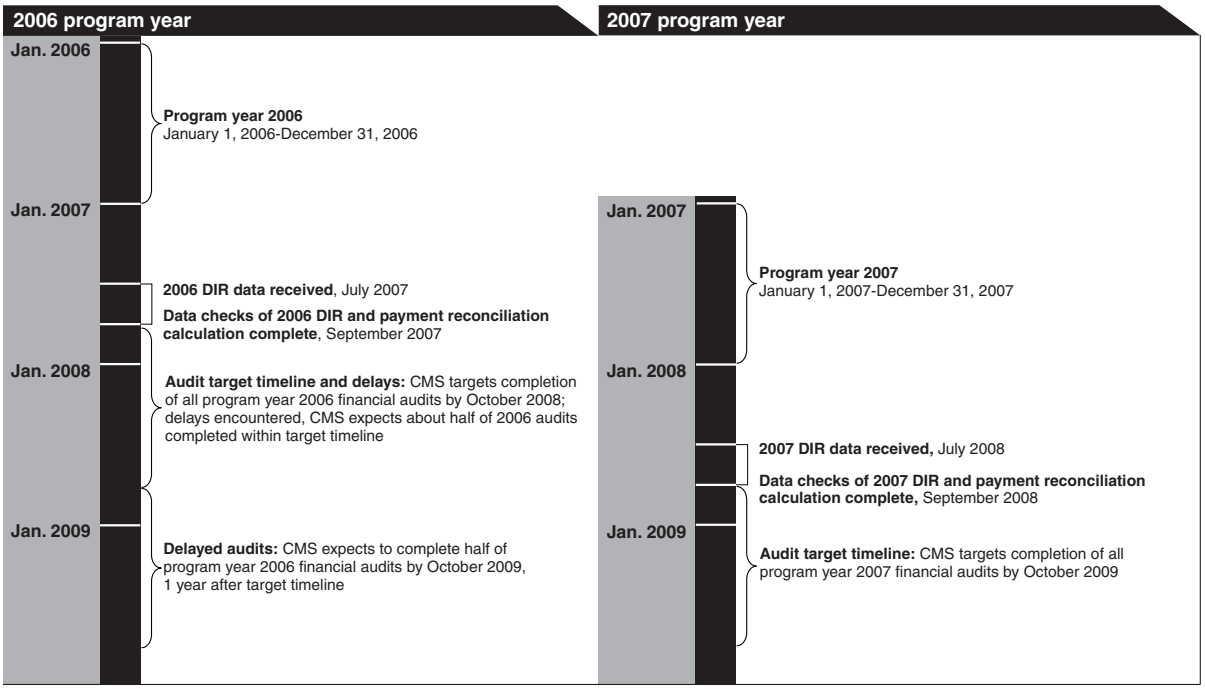
[14]For program year 2006, plans were not required to report certain DIR retained by PBMs. However, auditors were instructed to inform plans that beginning with program year 2007 all DIR, even if kept by a PBM, should be reported as DIR to CMS.

[15]The statutory requirements relating to the Medicare Part D audits do not specify a time frame for completing the audits. SSA section 1860D-12(b)(3)(C) (as added by the MMA) (codified at 42 U.S.C. § 1395w-112(b)(3)(C)); 42 C.F.R. § 423.504(d) (2007). CMS's target timeline is consistent with the timeline CMS established for Medicare Advantage plans. In commenting on a previous GAO report, CMS indicated that audits of Medicare Advantage organizations should be completed within 3 years from the time bids were accepted—about 22 months after the end of the program year. See GAO, *Medicare Advantage: Required Audits of Limited Value*, GAO-07-945 (Washington, D.C.: July 30, 2007).

[16]According to CMS officials, CMS spent $4.5 million to complete the first 81 of 169 program year 2006 financial audits and expects to spend $4.8 million to complete the remaining 88.

Figure 1: Financial Audit and Other DIR Data Oversight Timeline, Program Years 2006 and 2007



Source: GAO analysis of CMS information.

Variation in Defining and Reporting of Price Concessions Data May Present Oversight Challenges

CMS officials acknowledged that certain problems inherent in defining and reporting price concessions data may present challenges for oversight. For example, they told us that developing accurate assessments of the fair market values of administrative fees for services provided by sponsors and their PBMs presented a challenge because of differences in how these services are defined in sponsors' and PBMs' contracts with other entities.[17] Officials expected that as they gather information from completed audits, their understanding of the fair market value of administrative fees might improve; however, the complexity of and variation in contractual relationships will continue to make accurate assessments a challenge. Similarly, because of variation in contractual relationships, plan designs, and enrollee characteristics across plans, it may not be possible to establish guidance on how sponsors should allocate rebates between their Part D and other businesses that cover every circumstance. For example, certain drug rebates are awarded based on a plan's formulary.[18] Sponsors that use the same formulary for their Part D and other plans may choose to allocate rebates equally among them, whereas sponsors that use different formularies across various plans may choose an allocation method that accounts for the differences.

[17]By statute, CMS may not interfere in the negotiation of sponsors' contracts with PBMs and other entities, and therefore cannot dictate terms. SSA § 1860D-11(i) (as added by the MMA) (codified at 42 U.S.C. § 1395w-111(i)).

[18]A formulary is a list of drugs covered by the plan, which often gives preference to certain drugs over other drugs that treat the same condition.

Agency Comments and Our Evaluation

We received written comments on a draft of this report from HHS (see encl. I). HHS stated that the draft correctly characterized the financial audit program, but did not adequately emphasize the robustness of CMS's other oversight activities or the budget challenges that CMS faced in conducting its oversight. Specifically, HHS expressed concern that we did not adequately characterize CMS's data checks conducted prior to payment reconciliation, including their thoroughness and complexity. While we summarized the types of data checks CMS conducted, we did not include extensive detail, in part, because a document CMS provided that described the data checks was marked "confidential." However, in light of HHS's comments, we revised the report to reference the updated document describing the data checks that HHS provided along with its comments. We also revised the report to reflect that CMS believes the data checks will identify more than obvious problems and considers the data checks vital to ensuring confidence in the data prior to payment reconciliation. Although CMS conducts these data checks prior to payment reconciliation, we agree with HHS that the financial audits conducted after reconciliation provide the most complete review of the DIR data for accuracy. Regarding the budget challenges, HHS expressed concern that we did not adequately address the funding challenges CMS faced in carrying out its statutory audit requirements. Our report acknowledges that a portion of the financial audits of 2006 data were delayed due to financial constraints; however, a full analysis of the adequacy of CMS's budget was beyond the scope of this report. HHS also provided certain additional comments, including technical comments, which we incorporated as appropriate.

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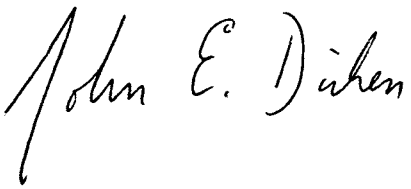
As arranged with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the date of this report. At that time, we will send copies to the Secretary of HHS, the Acting Administrator of CMS, and interested parties upon request. The report will also be available at no charge on GAO's Web site at http://www.gao.gov. If you or your staff have any questions regarding this report, please call me at 202-512-7114. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Randy DiRosa, Assistant Director; Rebecca Abela; Gerardine Brennan; Timothy Walker; and Margaret Weber were major contributors to this report.

Sincerely yours,



John E. Dicken
Director, Health Care

Enclosure

Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

SEP 19 2008

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

Dear Mr. Dicken:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "Medicare Part D Prescription Drug Coverage: Federal Oversight of Reported Price Concessions Data" (GAO-08-1074).

The Department appreciates the opportunity to review and comment on this report before its publication.

Sincerely,

for Vincent J. Ventimiglia, Jr.
Assistant Secretary for Legislation

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

SEP 16 2008

DATE:

TO: Vincent J. Ventimiglia, Jr.
Assistant Secretary for Legislation
Department of Health and Human Services

FROM: Kerry Weems
Acting Administrator

SUBJECT: Government Accountability Office (GAO) Draft Correspondence: "Medicare Part D Prescription Drug Coverage: Federal Oversight of Reported Price Concessions Data" (GAO-08-1074R)

Thank you for the opportunity to comment on the draft correspondence entitled, "Medicare Part D Prescription Drug Coverage: Federal Oversight of Reported Price Concessions Data (GAO-08-1074R)." As described in detail below, we believe we have a robust process for ensuring the accuracy of plan reported price concession data. Moreover, we have continued to enhance our pre-reconciliation and audit review procedures as we continue to gain experience with the program. While we feel that the Centers for Medicare & Medicaid Services (CMS) and GAO staffs have worked collaboratively on this correspondence, we want to share the following comments and concerns related to the depiction of CMS' oversight of the price concessions data.

While you have correctly characterized the financial audit program, your correspondence fails to represent the funding challenges CMS faced in carrying out the statutory one third financial audit requirements. We believe it is important to note that CMS made a request for funds, as part of a proposal to fund program integrity and oversight activities through an adjustment to discretionary spending totals, in fiscal year (FY) 2007 ($118 million) and FY 2008 ($183 million) and that in each year Congress failed to enact our budget request. This request would allow us to fully fund the required audits. Nevertheless CMS has taken measures to achieve timelier audit results with the funding levels available. We are revising the audit protocols for the remaining FY 2006 audits to perform them in the most efficient manner. We are eagerly awaiting our audit results. We fully expect that this information will prove helpful and will form the basis for future revisions to the financial audit protocol process.

We have several concerns regarding the characterization of our process for ensuring the reliability of the price concessions data used to determine Part D payments. In light of the challenges in ensuring the accuracy of payments that are dependent upon self-reported data, we have created and implemented a rigorous and comprehensive process for reviewing and validating these data. The first step of this two-step process involves in-depth review and

analysis of the Direct and Indirect Remuneration (DIR) data submitted by Part D sponsors prior to the Part D payment reconciliation. These reviews are effective in identifying and resolving potential errors in the DIR data and also hold Part D sponsors accountable for potential omissions or inaccuracies in their DIR data. This first step is vital to ensure that we have a certain level of confidence in the quality of the DIR data before using it in the determination of Part D payments. In recognition of the challenges other federal programs have faced in relying on similar types of data, we are also conducting audits in the second step of our process to perform the most rigorous and detailed review of these data possible. While this step is currently conducted after the Part D payment reconciliation, the results of the audits will allow CMS to adjust Part D payments and seek corrective action by Part D sponsors as appropriate.

Our process of conducting an initial review prior to payment followed by comprehensive post-payment audits mirrors the processes implemented under other federal programs faced with the similar data challenge of ensuring accurate and timely payments when payment is based upon self-reported data. For example, in the Fee-for-Service program, CMS performs data checks on the claims received, pays these claims as appropriate within the required timeframe, and then performs audits after the claims are paid to identify potential fraud and enable the agency to take corrective action as appropriate. While we acknowledge that our process will improve over time as the Part D program matures and we learn more about the DIR data, we are confident that this process will ensure accurate and timely payments.

In addition, the correspondence suggests that the purpose of the data reviews, which CMS conducts on the DIR data prior to Part D Payment Reconciliation, is to identify *obvious* problems. This description fails to adequately convey the complexity and thoroughness of the reviews and is not entirely accurate. While we admit that these reviews are limited by the data available to CMS prior to payment reconciliation, these data reviews are quite thorough. These reviews are designed to identify potential inaccuracies as well as omissions in the DIR data submitted to CMS. While audits are required to conduct the most complete review of the DIR data for accuracy, the discrepancies identified and addressed in these data reviews are by no means limited to obvious problems. Accordingly, we recommend the draft correspondence be revised to include a more in-depth explanation of the reviews conducted prior to payment reconciliation to better illustrate the purpose and scope of these reviews. A listing of these reviews is provided below. We note that as we gain experience with the data and reviews, we will refine and add reviews to better screen for potential errors and omissions in the DIR data. For example, during the review of the 2007 DIR data, we added three additional data reviews. A full list of these reviews is included as Attachment A.

Furthermore, we recommend that the correspondence be revised to include additional discussion of the resolution of problems identified in DIR data after payment reconciliation. We note that if any problems are identified in the DIR data after payment reconciliation, whether by CMS during the financial audits or by plan sponsors during their own internal audits and reviews, CMS has the option to re-open the Part D sponsor's payment reconciliation and recalculate its Part D payments based on the corrected DIR data.

Finally, the correspondence indicates that the DIR reporting guidance does not specify how sponsors should allocate price concessions. However, the correspondence does not take into

account the actions that we have taken to address the allocation of price concessions. In our guidance, we require Part D sponsors to apply a *reasonable* allocation methodology when allocating their DIR to the plan level. In addition, Part D sponsors are instructed to maintain documentation of the allocation methodologies used. While CMS has not currently provided guidance regarding appropriate or reasonable methodologies for allocating price concession on the DIR Report for Payment Reconciliation, we expect to provide guidance on this issue in the future. We are actively gathering information regarding the allocation methodologies used by Part D sponsors through the DIR data and our audits of these data. Specifically, beginning with the 2007 DIR Report for Payment Reconciliation, we have required Part D sponsors to provide a description of the methodologies used for allocating their DIR data. As we review this information and the results of the audits, we expect to be able to develop additional guidance for Part D sponsors regarding reasonable allocation methodologies for the DIR data reported to CMS.

Also, we have provided additional technical comments (see Attachment B).

Attachments

Attachment A – DIR Data Reviews
Attachment B – Technical Comments

ATTACHMENT A: DIR Data Reviews

1. **No DIR report submitted:** The CMS identifies active Part D plans with actual enrollment which did not submit a DIR Report for Payment Reconciliation.

2. **DIR reported less than or equal to total rebates on quarterly reporting:** The CMS compares the rebate amounts reported on the DIR report for each parent organization to the rebates reported on the quarterly rebate reports for the corresponding contract year. Parent Organizations with rebate amounts on the DIR report which are less than or equal to the rebate amounts reported on the quarterly rebate reports are identified as outliers.

3. **Total DIR Reported = $0:** The CMS reviews the DIR data to identify those Part D plans with $0 Total DIR reported on the DIR Report for Payment Reconciliation. Part D sponsors are asked to provide an explanation of why the plan had $0 DIR to report.

4. **DIR as a percent of total drug costs (High):** CMS compares the total DIR amount reported to the total gross covered drug cost reported on their Prescription Drug Event (PDE) records and their total enrollment for the contract year. Using these data, CMS identifies as outliers, Part D plans with unusually high total DIR as a percentage of total gross covered drug cost or per member per month.

5. **DIR as a percent of total drug costs (Low):** The CMS compares the total DIR amount reported by the Part D sponsor to the total gross covered drug cost reported on its Prescription Drug Event (PDE) records and its total enrollment for the contract year. Using these data, CMS identifies as outliers, Part D plans with unusually low total DIR as a percentage of total gross covered drug cost or per member per month.

6. **Negative Total DIR:** The CMS reviews the DIR data to identify those Part D plans with a total DIR value less than $0 reported on the DIR Report for Payment Reconciliation.

7. **Comments in All Other DIR text description:** On the DIR Report for Payment Reconciliation, Part D sponsors are permitted to report any applicable DIR that is not captured on the rest of the DIR report in the column DIR 7- "All Other DIR". However, Part D sponsors are required to provide a description of the price concession along with the associated dollar amount in the column "Other Text Description" for any DIR amount reported in the "All Other DIR" column. CMS reviews the descriptions provided in the "Other Text Description" column of the DIR Report to determine if the appropriate price concessions were included and to ensure that claim amounts for rejected PDE were not included on the report.

8. **All Other DIR as a percent of Total DIR (High):** The CMS compares the DIR reported in the "All Other DIR" column of the DIR Report for Payment Reconciliation to the total DIR amount reported. Those Part D plans with DIR data reported in the "All Other DIR" column which is unusually high as a percent total DIR reported are identified as outliers.

9. **DIR reported relative to rebates reported and projected in 2008 bids:** The CMS compares both the rebate amounts reported in the bids for baseline experience and the rebate amounts projected for the following contract year to the total DIR amount reported on the DIR Report for Payment Reconciliation. Contracts where either the 2006 base period experience rebate percentage or the projected 2008 base period rebate percentage differs significantly from the total DIR percentage are identified as outliers.

10. **Comparison to Prior Year's DIR Data (Beginning with 2007 DIR Data):** The CMS compares the total DIR for the prior contract year to the total DIR reported for the current contract year reported. To conduct this analysis, CMS determines a Part D plan's DIR relative to its total drug cost for both contract years. In addition, CMS compares each plan's average per member per month DIR for both contract years using the plan's enrollment data. Plans with significant changes in DIR from the previous contract year are identified as outliers.

11. **DIR Values Repeated Across Plans or Contracts (Beginning in 2007):** The CMS reviews the total DIR reported for the Part D plans offered under each contract to identify Part D contracts where the same non-zero DIR value is reported for all of the Part D plans under the contract. In addition, CMS reviews the DIR reported to identify Part D plans where the same DIR value was repeated across DIR categories.

12. **Top Ten Analysis (Beginning in 2007):** The CMS conducts additional reviews on the DIR data submitted by the 10 Parent Organizations with the greatest total Part D enrollment. Conference calls are conducted with the Part D sponsors to address any potential data discrepancies identified.

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