



June 1, 2010

TO: Marilyn Tavenner
Acting Administrator and Chief Operating Officer
Centers for Medicare & Medicaid Services

FROM: /Joseph J. Green/ for
Joseph E. Vengrin
Deputy Inspector General for Audit Services

SUBJECT: Medicare Part D – Prescription Drug Event Reconciliation Process
(A-18-08-30102)

This memorandum transmits the results of our performance audit of the Centers for Medicare & Medicaid Services' (CMS) Medicare Part D Prescription Drug Event (PDE) reconciliation process. We contracted with the independent certified public accounting firm of KPMG, LLP (KPMG), to perform the audit. The contract required that the audit be performed in accordance with auditing standards generally accepted in the United States of America.

Results of Performance Audit

On November 15, 2005, Medicare Part D, the prescription drug coverage program for senior and other eligible citizens, went into effect. Under this program, private health insurance companies and organizations (Plan sponsors) offer insurance coverage for prescription drugs in which Medicare and eligible Medicaid recipients can enroll. CMS contracted with Plan sponsors nationwide to offer the Part D benefits for qualified beneficiaries on January 1, 2006.

Our audit objectives were to determine whether CMS controls over payments to Plan sponsors, PDE records, and year-end reconciliation provided reasonable assurance that: (1) the inputs that drive the calculation of monthly payments are accurate and complete; (2) the Risk Adjustment Factor calculations by the Risk Adjustment Processing System are accurate; (3) monthly payments are accurately calculated and are tracked; (4) submitted PDE records are valid, accurate, and complete; (5) PDE data are complete before year-end reconciliation; and (6) Direct or Indirect Remuneration (DIR) reporting is accurate and complete.

CMS has designed a layered compliance framework that uses as inputs beneficiary reported complaints, internal data analysis results, audits, and other continuous oversight activities to take compliance action against Plan sponsors when needed. In addition, monthly payments are accurately being calculated and tracked. However, (1) the bid review and audit process needs

improvement to ensure that inputs to monthly payments are accurate and complete; (2) controls need to be improved to ensure that submitted PDE records are accurate and complete and PDE data are complete before year-end reconciliation; and (3) improved benchmarks and metrics are needed to ensure the completeness and accuracy of DIR before reconciliation.

The attached report contains detailed recommendations for strengthening CMS's internal controls and improving the effectiveness of its PDE Reconciliation process. CMS agreed with most of our recommendations. For those recommendations with which CMS did not agree, we either revised the report or provided clarification.

Monitoring of Audit Performance

We reviewed the performance audit by:

- evaluating the independence, objectivity, and qualifications of the auditors;
- reviewing the approach and planning of the audit;
- attending key meetings with auditors and CMS officials;
- monitoring the progress of the audit; and
- reviewing the auditors' reports.

KPMG is responsible for the attached auditors' report and the conclusions expressed in the report. Our monitoring review, as limited to the procedures listed above, disclosed no instances in which KPMG did not comply, in all material respects, with U.S. generally accepted government auditing standards.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that the Office of Inspector General (OIG) post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at <http://oig.hhs.gov>.

Please send us your final written management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Lori Pilcher, Assistant Inspector General for Grants, Internal Activities, and Information Technology Audits, at (202) 619-1175 or through email at Lori.Pilcher@oig.hhs.gov. Please refer to report number A-18-08-30102 in all correspondence.

Attachment

cc:

Jonathan Blum

Deputy Administrator and Director
Center for Medicare, CMS

Deborah Taylor

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CENTERS FOR MEDICARE AND
MEDICAID SERVICES

Prescription Drug Event (PDE) Reconciliation
Process Performance Audit

Prepared for the Office of Inspector General
U.S. Department of Health and Human Services

By KPMG LLP

As of October 23, 2009

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EXECUTIVE SUMMARY

April 30, 2010

Mr. Edward Meyers
Director, Information Systems Audit and Advanced Techniques Staff
U.S. Department of Health and Human Services
Office of Inspector General, Office of Audit Services (OIG/OAS)
330 Independence Avenue SW
Washington, DC 20201

Mr. Meyers:

This report presents the results of our work conducted to address the performance audit objectives relative to Centers for Medicare and Medicaid's (CMS) Prescription Drug Event (PDE) Reconciliation Process. Our fieldwork was performed during the period of March 10, 2009 through October 23, 2009, and our results are as of September 30, 2009.

We conducted this performance audit 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 recommendations based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and recommendations based on our audit objectives.

This executive summary provides a brief overview of our performance audit objectives and methodology, and a summary of results. The remainder of our report more fully describes our audit scope and performance audit results.

This performance audit focused on assisting the OIG in understanding the design and effectiveness of CMS's controls to (1) accurately calculate and track monthly plan sponsor payments, (2) identify incomplete and/or inaccurate PDE records received, and (3) determine completeness of Prescription Drug Event records prior to year-end reconciliation for the purpose of determining risk-sharing amounts and adjustments to risk corridors.

To evaluate CMS's controls over payments to plan sponsors, PDE records, and year-end reconciliation, we developed audit procedures to determine whether internal controls provide reasonable assurance that:

- The inputs that drive the calculation of monthly payments to plan sponsors are accurate and complete
- The Risk Adjustment Factor (RAF) calculations by the Risk Adjustment Processing System are accurate
- Monthly payments are accurately calculated and are tracked
- Submitted PDE records are valid, accurate, and complete
- PDE data is complete prior to year-end reconciliation

Direct or Indirect Remuneration (DIR) reporting is accurate and complete.



To conduct our performance audit, we developed a risk-based work program that included steps to address each audit objective. We used the following references, Control Objectives for Information and Technology, the CMS Prescription Drug Benefits Manual, and the Medicare Modernization Act (MMA), to help identify the control requirements and to obtain an understanding of the required processes, procedures, and controls. We conducted the audit procedures for each of the audit objectives by performing inquiries, making observations, and examining documentation. We used a sampling approach in instances where a test of controls was conducive to sampling.

Based on our procedures, we noted that CMS has designed a layered compliance framework that uses as inputs beneficiary reported complaints, internal data analysis results, audits, and other continuous oversight activities to take compliance action against plan sponsors where needed. In addition, we understand that the current Part D program design disadvantages CMS from an internal control perspective as critical data needed for year-end reconciliation, including PDE records and DIR information, is self-reported by plan sponsors. In addition, CMS is limited in its ability to react to plan sponsor bid audit results due to the Program's complexity and statutory framework. Furthermore, while CMS performs statutorily mandated audits of one-third of plan sponsors for each year, these reviews do not provide for timely assessment of the accuracy and validity of plan sponsor reported information. However, CMS should do more to close the inherent internal control disparity that exists in the program. As such, we encourage CMS to implement more near real-time auditing and monitoring controls, seek opportunities to expand access to and the use of point-of-sale information, and improve DIR reporting and auditing to the extent possible. Specifically, we noted the following four findings and recommendations designed to help improve the completeness and integrity of plan sponsor reported data.

1. CMS Should Strengthen Controls Over the Bid Review and Audit Process

Private health insurance companies (plan sponsors) submit bids annually to CMS to participate in the Part D program. These bids outline the pricing and benefits for the plans the plan sponsor will offer and form the initial basis for determining monthly subsidy payments to the plan sponsor. Subsidy payments are estimated amounts paid by CMS to plan sponsors throughout the year and are reconciled after year-end with actual drug costs.

The CMS Office of the Actuary (OACT) reviews and audits bids submitted by plan sponsors. OACT contracts with actuarial firms to review bids to ensure plan sponsors have followed the Part D Bid Guidance and submitted all necessary support. After OACT approves the bids, it chooses a selection of plans for audit and requests an actuarial firm to conduct an in-depth review of the actuarial assumptions used to calculate the bid.

We performed procedures to determine the design and effectiveness of the controls CMS has in place to ensure bids were properly reviewed and we determined that:

- Prior to approving bids in 2008, OACT did not review all bids to verify that all required parts (subreviews) of the bid were documented as being complete in Health Plan Management System. Specifically, we noted that from a sample of 40 bids, 1 bid was approved by OACT even though not all of the required subreviews were documented as being complete. Not reviewing all subreviews for completeness increases the risk that CMS may approve bids prior to all parts of the review process being completed.
- Inaccuracies found by actuaries as part of the bid audits do not subsequently adjust the monthly payments that submitting plan sponsors will receive, which are based on the original bid. As a result, plan sponsors will continue to receive payments based on bids not prepared in accordance



with CMS instructions. These payments may only be partially recovered during the reconciliation process.

- The actuarial firms performing bid reviews are contractually required to be independent of the plan sponsors whose bids they are reviewing; however, CMS does not require the individual actuaries to confirm their independence to CMS for each bid review or audit. Lack of independence could compromise the objectivity of the review.

2. CMS Should Improve Controls Over the Accuracy and Completeness of PDE and True-Out-Of-Pocket (TrOOP) Accumulation

Plan sponsors submit a PDE record to CMS for each prescription that has been filled for a beneficiary enrolled in the plan sponsor's Part D plan. The PDE record contains information that CMS uses to reconcile monthly subsidy payments made to plan sponsors with actual program cost data. We performed procedures to determine the design and effectiveness of the controls CMS has in place to detect inaccurate PDE records and oversee the TrOOP facilitator and data exchanges with other agencies. We determined that:

- CMS did not have systematic controls to effectively detect errors in PDE record fields that are used in the year-end reconciliation and manual controls currently in place to detect inaccurate PDE records do not detect all discrepancies. This may result in PDE errors remaining undetected, which in turn could result in under- or over-payments to plan sponsors.
- The current Part D benefit infrastructure does not provide CMS access to point-of-sale and plan data to determine whether PDE records are valid and claims are adjudicated in accordance with the plan design. CMS has developed a PDE outlier analysis program. Although this control has identified drug cost reporting issues at plans, it does not operate at a level of precision and scope to compensate for the lack of automated controls.
- CMS did not perform active oversight of the TrOOP Facilitator, a third-party contractor retained by CMS to facilitate the exchange of TrOOP and secondary coverage information between plan sponsors. Secondary coverage impacts TrOOP costs, which in turns impact the coverage amounts reported in PDE records.
- CMS did not monitor its data exchange with the Social Security Administration for Supplemental Security Incomelow-income eligibility data. The completeness and accuracy of this information is important for plan sponsors to submit accurate PDE records.

3. CMS Should Strengthen Controls to Ensure Completeness and Accuracy of DIR Data Prior to Reconciliation

In addition to monthly subsidy payments and PDE records, CMS also uses information about DIR in its year-end reconciliation of Part D program costs and payments. DIR consists of discounts, rebates, and other price concessions on drugs that lower the plan sponsors' net cost of drugs. Plan sponsors submit DIR information quarterly and after year-end. The year-end totals include actual DIR and estimated DIR the plan sponsor expects to receive after the reporting date. We performed procedures to determine the design and effectiveness of controls CMS had in place to detect inaccurate DIR information submitted by plan sponsors, and we determined that:

- CMS's controls to detect inaccurate DIR may not detect all items needing follow-up because the thresholds for follow-up are set relatively high. As a result, not all significant potential discrepancies may be flagged for follow-up. If DIR is understated, and CMS's controls fail to



detect the understatement, a plan's risk corridor payment would be overstated and the plan sponsor could receive a larger year-end payment from CMS than that which it was entitled to..

- Plan sponsors are also not required to update estimated DIR information submitted to CMS once actual amounts are known. Therefore, CMS does not receive final DIR information from plan sponsors (or other sources) to accurately reconcile costs and payments prior to reconciliation.

4. CMS Should Conduct More Plan Sponsor Audit Procedures Throughout The Benefit Year

The CMS Office of Financial Management (OFM) performs audits of plan sponsors to help ensure that plan sponsors correctly administer the Part D benefits and that plan sponsor data reported to CMS is complete and accurate. Additionally, CMS Center for Drug and Health Plan Choice (CPC) conducts operational audits throughout the benefit year. Those audits focus on plan sponsor procedural compliance with selected chapters of the Part D Manual. CPC also performs audits of diagnosis data (RADV audits) for Medicare Advantage plans and validates the mathematical accuracy of the RAF calculations. We performed procedures to determine the design and effectiveness of CMS's audit activities and determined that:

- CMS does not perform audit activities throughout the current benefit year that focus on financial data that are key to year-end reconciliation, such as PDE records, DIR reporting and TrOOP accumulation. By design, OFM's audit activities start after year-end reconciliation is complete. OFM audits are intended to satisfy MMA audit requirements but are not an effective control to timely detect inaccuracies in PDE, TrOOP, and DIR.
- CMS has not formally taken compliance action on audit results in a timely manner. The first compliance letters to plan sponsors based on OFM audit results of 2006 data were not sent by CPC until September 2009. The delay in formally communicating audit results may delay corrective action by plan sponsors to avoid future errors.
- The Medicare Enrollment Database (EDB) extract used by the Risk Adjustment System contractor to calculate RAFs and the EDB extract used by the validation contractor to validate the RAF calculations are not created at the same time. This results in timing differences between the two sets of data making the identification and analysis of discrepancies more difficult.

The findings and related recommendations are presented in the Results section of this report. Together, the recommendations are designed to help improve the effectiveness of the reconciliation process by CMS, and we encourage timely implementation of recommendations. The Acting Administrator's written response dated March 11, 2010, to our draft report dated December 3, 2009, is included in Appendix C. Overall, the response was consistent with our understanding of the facts that served as the basis for the updated findings and recommendations made within this report. In cases where CMS did not agree with a recommendation, we either revised or provided clarification accordingly. We did not conduct any procedures to verify the changes to processes and controls represented by management.

This performance audit did not constitute an audit of financial statements in accordance with *Government Auditing Standards*. KPMG LLP (KPMG) was not engaged to, and did not render an opinion on CMS's internal controls over financial reporting or over financial management systems (for purposes of OMB's Circular No. A-127, *Financial Management Systems*, July 23, 1993, as revised). KPMG cautions that projecting the results of our evaluation to future periods is subject to the risks that controls may become inadequate because of changes in conditions or because compliance with controls may deteriorate.



We thank CMS management for their participation in this audit. Their time and participation allowed for a constructive exchange of ideas to improve the Part D Program internal control environment.

Sincerely,

KPMG LLP

BACKGROUND

On November 15, 2005, Medicare Part D, the prescription drug coverage program for seniors and other eligible citizens, went into effect. Under this program, private health insurance companies and organizations (plan sponsors) offer insurance coverage for prescription drugs in which Medicare recipients can enroll. CMS contracted with plan sponsors nationwide to offer these plans and began providing benefits for qualified beneficiaries on January 1, 2006. In addition to offering a basic benefit package as defined by law, most plan sponsors offer enhanced plans with additional benefits such as differing copayments and drug coverage. The Medicare Part D program differs from other entitlement programs in that it operates on a cost-sharing basis. The amount the U.S. government contributes to an individual's prescription drug claim varies depending on the amount of "total drug spend" incurred by the plan and "total out-of-pocket cost" incurred by the beneficiary. The plan sponsor collects beneficiary premiums and settles pharmacy and other distribution costs.

To fulfill the U.S. government's obligation to the program, CMS makes payments to plan sponsors on a monthly basis through estimated subsidy payments and, where needed, at year-end as a result of the payment reconciliation process. The reconciliation process compares estimated subsidy payments made to plan sponsors throughout the year with the cost data submitted by plan sponsors through Prescription Drug Event (PDE) records and Direct or Indirect Remuneration (DIR) data to determine any residual payments required by CMS to plan sponsors or plan sponsors to CMS. The reconciliation process relies on four major data sources: the sum of payments made to plan sponsors throughout the year, final updated plan enrollment, PDE records from plan sponsors, and DIR. These inputs into the reconciliation process are further discussed in Appendix A.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objectives

This performance audit focused on assisting the Office of the Inspector General (OIG) in understanding the design and effectiveness of CMS's controls to (1) accurately calculate and track monthly plan payments, (2) identify incomplete and/or inaccurate PDE records received, and (3) determine completeness of PDE records prior to reconciliation for the purpose of determining risk-sharing amounts and adjustments to risk corridors.

To evaluate CMS's controls over payments to plan sponsors, PDE records, and year-end reconciliation, we developed audit procedures to determine whether internal controls provide reasonable assurance that:

- The inputs that drive the calculation of monthly payments to plan sponsors are accurate and complete
- The RAF calculations by the Risk Adjustment Processing System are accurate
- Monthly payments are accurately calculated and are tracked
- Submitted PDE records are valid, accurate, and complete
- PDE data is complete prior to year-end reconciliation
- DIR reporting is accurate and complete.

Scope

Our performance audit focused on evaluating controls operated by CMS over the processing of monthly payments and controls over the inputs into monthly payments and the year-end reconciliation. Our Washington, D.C. office conducted fieldwork at CMS offices in Baltimore, Maryland, during the period from March 10, 2009

to October 23, 2009. During this period, we interviewed personnel and examined evidence pertaining to the CMS controls over monthly payments and inputs to the year-end reconciliation that were in place for the fiscal year beginning October 1, 2008 through September 30, 2009. Our work program included procedures to test CMS's controls that were relevant to our performance audit objectives. Our procedures did not extend to controls operated by CMS's contractors (i.e., the TrOOP Facilitator, Palmetto GBA, Acumen LLC), other agencies, or state governments, and were limited to control activities performed by CMS.

Methodology

To conduct our assessment, we developed a work program that included steps to address each audit objective. We used the following references, Control Objectives for Information Technology, the CMS Prescription Drug Benefits Manual and the Medicare Modernization Act (MMA), to help identify the control requirements and best practices and to obtain an understanding of the required reconciliation processes, implemented procedures, and related controls. The U.S. Department of Health and Human Services OIG reviewed and approved our audit program prior to the commencement of on-site fieldwork. Our work program was designed to address the specified audit objectives and included procedures to evaluate CMS's application package review process, data analysis procedures, plan sponsor audit activities, and process for creating and tracking corrective action plans. Our approach to conducting these procedures included performing inquiries, making observations and examining documentation. We used a sampling approach in instances where a test of controls was conducive to sampling.

RESULTS

This report summarizes our findings resulting from our evaluation of the controls over CMS's Part D Reconciliation process. For each of our findings, we provide recommendations for corrective actions by CMS, as well as CMS management's response to those recommendations.

1. CMS Should Strengthen Controls Over the Bid Review and Audit Process (OARS 09-01)¹

Conditions

The CMS Office of the Actuary (OACT) reviews and audits bids submitted by plan sponsors. OACT contracts with actuarial firms to review bids to ensure plan sponsors have followed the Part D Bid Guidance and submitted all necessary support. After OACT approves the bids, it chooses a selection of plans for audit and requests an actuarial firm to conduct an in-depth review of the actuarial assumptions used to calculate the bid.

We performed procedures to determine the design and effectiveness of the controls CMS has in place to ensure bids were properly reviewed. We determined that:

- (i) Prior to approving bids in 2008, OACT did not review all bids to verify that all required parts (subreviews) of the bid were documented as being complete in Health Plan Management System (HPMS). Specifically, we noted that from a sample of 40 bids, one bid was approved by OACT even though not all of the required subreviews were documented as being complete.
- (ii) Inaccuracies found by actuaries as part of the bid audits do not subsequently adjust the monthly payments that submitting plan sponsors will receive, which are based on the original bid.

¹ We have referenced our findings with a sequential Objective Attribute Recap Sheet (OARS) number in the format "OARS YY-*nn*" where "YY" is fiscal year and "*nn*" is a sequential number.

- (iii) The actuarial firms performing bid reviews are contractually required to be independent of the plan sponsors whose bids they are reviewing; however, CMS does not require the individual actuaries to confirm their independence to CMS for each bid review or audit.

Causes

- (i) Due to a large number of bids in 2008, OACT did not have the resources to review every plan's bid to ensure that all required bid subreviews were complete prior to approving a plan's bid. OACT management informed us that for calendar year 2008, they performed such a review only for a selection of bids and that starting in calendar year 2009, OACT would start to review all bids to verify that all required bid subreviews were documented as being complete.
- (ii) Due to the statutory framework and complexities of the MMA Part D program, CMS is limited in its ability to affect changes to approved bids based on the results of a bid audits The MMA requires that prospective payments to plans and beneficiary premiums both be calculated using a prescribed formula based on a plan's approved bid amount, the national average monthly bid amount, and the Part D base beneficiary premium. Therefore, making retroactive changes to prospective payment amounts would affect bid amounts and beneficiary premiums not only for the affected plan, but could also affect the regional benchmarks or the national average bid amount and could ultimately create an uneven competitive market for plans since not all plans are subject to audit each year.
- (iii) OACT does not require actuarial firms to certify the independence of the individual actuaries working on bid reviews or bid audits.

Criteria

For conditions (i) and (iii):

42 CFR Part 423.272 states: (1) Application of revenue requirements standard. CMS approves a bid submitted under §423.265 only if it determines that the portions of the bid attributable to basic and supplemental prescription drug coverage are supported by the actuarial bases provided and reasonably and equitably reflect the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under section §423.329(c).

For condition (ii):

42 CFR Part §423.346 establishes requirements for reopening reconciliation including errors, fraud, or a good cause for reopening reconciliation as it states: (a) CMS may reopen and revise an initial or reconsidered final payment determination (including a determination on the final amount of direct subsidy described in §423.329(a)(1), final reinsurance payments described in §423.329(c), the final amount of the low-income subsidy described in §423.329(d), or final risk corridor payments as described in §423.336)—(1) For any reason, within 12 months from the date of the notice of the final determination to the Part D sponsor; (2) After that 12-month period, but within 4 years after the date of the notice of the initial or reconsidered determination to the Part D sponsor, upon establishment of good cause for reopening; or (3) At any time, in instances of fraud or similar fault of the Part D sponsor or any subcontractor of the Part D sponsor. (b) For purposes of this section, CMS will find good cause if—(1) New and material evidence that was not readily available at the time the final determination was made is furnished; (2) A clerical error in the computation of payments was made; or (3) The evidence that was considered in making the determination clearly shows on its face that an error was made. (c) For purposes of this section, CMS will not find good cause if the only reason for reopening is a change of legal interpretation or administrative ruling upon which the final determination was made.

Effects

- (i) If OACT does not verify that all review steps have been completed prior to approving bids, the risk is increased that bids may be approved without being subject to all the required subreviews. This may result in bids with errors being accepted.
- (ii) When results of bid audits have no impact on monthly payments or year-end reconciliation, plan sponsors may benefit from an overbid by retaining a portion of the excess payments to them through risk sharing with CMS at year-end reconciliation.
- (iii) If individual actuaries are not independent of the plan sponsor when conducting bid reviews and bid audits, actuaries may have an actual or perceived bias when reviewing and auditing bids.

Recommendations

We recommend that:

- (i) Prior to approving the bid, CMS continues to ensure that the bid reviews and subreviews are documented as complete and that the review results support the recommendation to approve the bid. CMS should consider implementing automated checks in its data collection system(s) to aid in ensuring each required bid subreview is recorded as complete prior to allowing CMS to document approval of the bid.
- (ii) OACT works with Center for Drug and Health Plan Choice (CPC), Office of Financial Management (OFM), and OIG to correlate results from bid audits with other oversight activity outcomes (e.g., outlier analysis, operation audits, and OFM audits) to help ensure bid audit results (contract-specific or in aggregate) are considered in ongoing compliance monitoring of plan sponsors and year-end reconciliation.
- (iii) CMS requires individual actuaries to certify their independence of the plan sponsor prior to performing bid reviews or bid audits.

Management Response

CMS concurred with some recommendations and did not concur with others. CMS partially concurred with recommendations (i) and (ii) and concurred with recommendation (iii). CMS did not concur with our recommendations for including automated edits in HPMS and reviewing its options to recover payments as a result of bid audits.

Auditor's Comments

In response to CMS's comments, we revised the wording of recommendations (i) and (ii). We also removed one recommendation that CMS did not concur with and agreed with CMS's position on this matter as stated on page 5 of CMS's response, attached as Appendix C.

2. CMS Should Improve Controls Over the Accuracy and Completeness of PDE and True-Out-Of-Pocket (TrOOP) Accumulation (OARS 09-02)

Conditions

Plan sponsors submit a PDE record to CMS for each prescription that has been filled for a beneficiary enrolled in the plan sponsor's Part D plan. The PDE record contains information that CMS uses to reconcile monthly subsidy payments made to plan sponsors with actual program cost data. We performed procedures

to determine the design and effectiveness of the controls CMS has in place to detect inaccurate PDE records and provide oversight of the TrOOP facilitator and data exchanges with other agencies. We determined that:

- (i) CMS did not have systematic controls to effectively detect errors in the calculation of PDE payment and cost fields² that are used in the year-end reconciliation. In addition, CMS does not have automated controls in place to detect instances where plans may be failing to maintain accurate TrOOP and Drug Spend balances.
- (ii) The current Part D benefit infrastructure does not provide CMS access to point-of-sale and plan data to determine whether PDE records are valid and claims are adjudicated in accordance with the plan design. CMS has developed a PDE outlier analysis program. Although this control has identified drug cost reporting issues at plans, it does not operate at a level of precision and scope to compensate for the lack of automated controls.
- (iii) CMS did not perform active oversight of the TrOOP Facilitator, a third-party contractor retained by CMS to facilitate the exchange of TrOOP and secondary coverage information between plan sponsors. Specifically, CMS's oversight of the TrOOP Facilitator was not suitably designed to help ensure that secondary payment reporting (N1) and account transfer (FIR) transactions sent to the plans were as complete and accurate as possible. CMS's oversight activities of the TrOOP Facilitator were limited to weekly status meetings to discuss TrOOP Balance Transfer Reports that summarized, by plan sponsor, total counts of accepted and rejected FIR transaction responses. These reports did not provide CMS visibility into the completeness of FIR transactions or the effectiveness of the N1 process.
- (iv) CMS did not monitor its data exchange with the Social Security Administration (SSA) for Supplemental Security Income (SSI) low-income eligibility data to detect any errors that need to be resolved.

Causes

- (i) CMS's cost edits reviewed in the Drug Data Processing System (DDPS) are designed to detect PDEs with costs and payments that do not balance or that have zero cost. CMS has not implemented additional cost edits to detect the miscalculation of cost fields such as Covered D Plan Paid (CPP) Amount, Gross Drug Cost Below the Out-of-Pocket Threshold (GDCB), and Gross Drug Cost Above the Out-of-Pocket Threshold (GDCA) because such edits are technically difficult to implement due to the high volume of transactions. Such edits would require DDPS to have access to year-to-date balances for accumulated drug cost and accumulated TrOOP for each PDE record being processed as of the point-in-time that the underlying claim was adjudicated. CMS's lack of access to accumulated drug cost and TrOOP balances for each PDE record received also contributes to CMS's inability to determine whether PDE records are accurately calculated.
- (ii) Due to a lack of resources and the technical difficulty of developing and implementing a system to capture point-of-sale events, CMS lacks insight into point-of-sale events, and therefore does not have the necessary data to assess the accuracy, completeness, and validity of PDE data received from plan sponsors.
- (iii) CMS does not exercise effective oversight of the TrOOP Facilitator due to a lack of resources and due to known issues that prevent the TrOOP Facilitator from generating a complete stream of N1 transactions. Some of these issues arise because insurance companies are not required by law to share with CMS data on their Medicare supplemental prescription drug insurance enrollees and beneficiaries may not always indicate secondary coverage through annual coordination of benefits surveys. Insurance companies that

² Relevant cost fields include: CPP - Covered D Plan Paid Amount; GDCB - Gross Drug Cost Below the Out-of-Pocket Threshold, and GDCA - Gross Drug Cost Above the Out-of-Pocket Threshold.

choose to share data with CMS's TrOOP Facilitator on their Medicare supplemental prescription drug insurance enrollees do so through voluntary data sharing agreements with CMS. For those non-Part D insurance companies that choose not to share their enrollment data with CMS, the TrOOP Facilitator is unable to positively identify B transactions as secondary payments on a Part D claim and consequently cannot generate N1 transactions. Therefore, the flow of N1 transactions from the TrOOP Facilitator to the plan sponsors may be incomplete.

- (iv) CMS does not monitor the weekly uploads from the SSA of data on SSI recipients to detect any errors that need to be resolved because the SSI eligibility data uploads experience a high incidence of rejected records (accounting for approximately 80 percent of total record volume) that do not need to be resolved and a low incidence of errors that would require manual intervention and correction. The high error volume occurs because SSA provides CMS upload files of all SSI recipients that have not been deemed for low-income subsidy (LIS), regardless of whether the beneficiaries are Medicare eligible. SSA has scheduled changes to its interface with CMS to be made in 2010.

Criteria

For conditions (i) and (ii):

42 CFR Part 423.503 states: (d) Oversight of continuing compliance. (1) CMS oversees a Part D plan sponsor's continued compliance with the requirements for a Part D plan sponsor.

For conditions (i), (ii), (iii), and (iv):

Section 2 of the Federal Managers Financial Integrity Act of 1982 states: ... internal accounting and administrative controls of each executive agency shall be established in accordance with standards prescribed by the Comptroller General, and shall provide reasonable assurances that:

- (i) Obligations and costs are in compliance with applicable law
- (ii) Funds, property, and other assets are safeguarded against waste, loss, unauthorized use, or misappropriation
- (iii) Revenues and expenditures applicable to agency operations are properly recorded and accounted for to permit the preparation of accounts and reliable financial and statistical reports and to maintain accountability over the assets

For conditions (i) and (iii): 42 CFR Part 423.104 states: coverage limit is equal to:

- (i) For 2006. \$2,250
- (ii) For years subsequent to 2006. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of \$10
- (iii) Cost-sharing between the initial coverage limit and the annual out-of-pocket threshold
Coinsurance for costs for covered Part D drugs above the initial coverage limit described in paragraph (d)(3) of this section and annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section that is equal to 100 percent of actual costs
- (iv) Protection against high out-of-pocket expenditures. (i) After an enrollee's incurred costs exceed the annual out-of-pocket threshold described in paragraph (d)(5)(iii) of this section, cost sharing equal to the greater of:
 - (A) Copayments. (1) In 2006, \$2 for a generic drug or preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i) of the Act) and \$5 for any other drug; and (2) For subsequent years, the copayment amounts specified in this paragraph for the previous

year increased by the annual percentage increase described in paragraph (d)(5)(iv) of this section and rounded to the nearest multiple of 5 cents

- (B) Coinsurance. Coinsurance of 5 percent of actual cost.

Effects

- (i) If the CPP amount on a plan's PDE records is miscalculated, the amount of payment due to or from the plan at year-end reconciliation may be inaccurate. For example, if CPP is overstated, risk corridor costs will also be overstated, which may cause the plan to receive a year-end reconciliation payment from CMS that is too high. If GDCA and GDCB on a plan's PDE records are miscalculated, the amount of payment due to or from the plan at year-end reconciliation may be inaccurate. For example, if GDCA is overstated, at year-end reconciliation the plan may receive a Reinsurance Subsidy payment from CMS that is too high. If GDCB is overstated, then DIR would be underallocated to GDCA, causing GDCA net of DIR to be overstated, which may cause the Reinsurance Subsidy payment at year-end reconciliation to be too high. In addition, by not operating controls to detect instances where plans may be failing to maintain accurate TrOOP and Drug Spend balances, CMS may not detect instances where plans are adjudicating claims inaccurately and submitting inaccurate PDE records.
- (ii) Outside of plan audits or any ad hoc requests for data to plan sponsors, CMS is dependent on plan sponsors to provide accurate and valid PDE data. CMS's lack of access to the necessary data to independently determine if PDE records are accurately calculated diminishes the effectiveness of CMS's oversight of the accuracy of plan sponsors' calculation of PDE records and of the underlying claims.
- (iii) Without complete information of supplemental insurance coverage, insight into point-of-sale events, and a program for overseeing the TrOOP Facilitator, TrOOP amounts accumulated by plan sponsors may be inaccurate, which in turn would affect the accuracy of plan-sponsor-reported PDE records.
- (iv) By not monitoring the weekly uploads from SSA of SSI eligibility data to detect any errors that need to be resolved, any errors that do require manual intervention and correction may not be resolved and the claims of LIS-eligible SSI recipients may not be adjudicated using LICS rules, resulting in inaccurately calculated claims and PDE records for the affected beneficiaries.

Recommendations

We recommend that:

- (i) CMS develops and implements system-based edits to prevent and detect errors in the calculation of PDE payment and cost fields that are used in the year-end reconciliation, such as CPP, GDCB, and GDCA. We acknowledge the technical difficulty of implementing such edits, especially in real-time. Therefore, we recommend that to incrementally improve controls over the calculation of PDE fields that are key to the year-end reconciliation, CMS should consider the following interim steps:
 - Adding fields to the PDE record layout for plans to report drug spend and TrOOP accumulator balances on every PDE record, and thereby using plan-sponsor-reported accumulator balances as the basis for detective cost and payment field edits (i.e., CPP, GDCB, and GDCA)
 - Developing, outside of the DDPS, an analysis mechanism to detect inaccurate payment and cost fields for a subset of PDE records based on CMS's recalculation of CPP, GDCB, and GDCA fields and independent accumulation of TrOOP and Drug Spend balances. As CMS refines the operation of such a detective control, it could then incrementally increase the volume of PDE records recalculated and ultimately implement real-time preventative payment and cost field edits.
- (ii) CMS studies the feasibility of obtaining and using point-of-sale data in the determination of monthly payments, to conduct near real-time validation of PDE records, and to anticipate year-end program costs.

We recommend that the study focus on the technical and programmatic aspects of real-time point-of-sale data collection and determine the opportunities, limitations, and cost-benefits of enhancing automated controls over PDE record validation while considering current, mostly ad hoc, data validation processes. The study should consider the current Part D program design and propose near- and longer-term solutions to help optimize Part D program real-time monitoring controls in a cost-effective manner.

- (iii) CMS implements a formal oversight program of the TrOOP Facilitator and continues to work with insurers to encourage the sharing of enrollee information and considers obtaining additional point-of-sale transaction information to allow comparison of the plan sponsor and pharmacy-reported information and to anticipate the number of outstanding PDE records.
- (iv) CMS implements a control to monitor the weekly uploads from the SSA of SSI eligibility data to detect and correct any errors that require manual intervention to be resolved.

Management Response

CMS concurred with recommendations (i), (ii), and (iv). With respect to recommendation (iii), CMS notes that unless other insurers supplemental to Medicare establish unique identifiers for each separate plan they offer, claims that are supplemental to Part D cannot be distinguished from all others. As a result, the TrOOP Facilitator's receipt of other payer claims information will not translate into the creation of additional Nx transactions, specifically if the additional claims cannot be matched with Part D beneficiaries. Until process improvements are in place, CMS does not agree that Nx transactions should be compared to reported PDE or used for estimating the number of PDEs. CMS will continue to encourage other payers to establish and use unique identifiers.

Auditor's Comments

We agree with CMS' commentary on recommendation (iii) and encourage CMS to lead process improvement efforts.

3. CMS Should Strengthen Controls to Ensure Completeness and Accuracy of DIR Prior to Reconciliation (OARS 09-03)

Conditions

In addition to monthly subsidy payments and PDE records, CMS also uses information about DIR in its year-end reconciliation of Part D program costs and payments. DIR consists of discounts, rebates, and other price concessions on drugs that lower the plan sponsors' net cost of drugs. Plan sponsors submit DIR information quarterly and after year-end. The year-end totals include actual DIR and estimated DIR the plan sponsor expects to receive after the reporting date. We performed procedures to determine the design and effectiveness of controls CMS had in place to detect inaccurate DIR information submitted by plan sponsors and we determined that:

- (i) CMS's controls to detect inaccurate DIR may not detect all items needing follow-up because the thresholds for follow-up are set relatively high. For example, CMS's DIR checks for 2007 included comparing a plan's reported DIR as a percent of total drug costs to a plan's prior year DIR reporting. In another DIR check, CMS flags reported DIR of less than 2 percent or greater than 50 percent of gross drug costs as outlier DIR reports needing follow-up. As a result, not all significant potential discrepancies may be flagged for follow-up.
- (ii) Plan sponsors are also not required to update estimated DIR information submitted to CMS once actual amounts are known. Therefore, CMS does not receive final DIR information from plan sponsors (or other sources) to accurately reconcile costs and payments prior to reconciliation.

Causes

- (i) CMS is limited to a three-week period each year between the annual plan sponsor DIR reporting deadline and end-of-year reconciliation to review and accept plan sponsors' annual DIR reports. The limited time available to review plan sponsors' DIR reports limits the rigor of CMS's review of DIR reports. Also, generally actual DIR is not known by plan sponsors until after year-end reconciliation and consequently plan sponsors report estimated DIR to CMS. In addition, CMS does not receive regular confirmation from Pharmacy Benefit Managers (PBMs) and manufacturers on DIR data reported by plans. Since each plan has the ability to negotiate its own rebates and discounts with manufacturers and PBMs, it may be difficult to identify reporting issues without information from PBMs and manufacturers. In addition, PBMs and manufacturers may not have full visibility into how rebates and discounts are allocated for each plan and individual drug rebate information is considered proprietary information.
- (ii) CMS policies do not require submission of final DIR information.

Criteria

42 CFR Part 423.308 states: For the purposes of this subpart, the following definitions apply: Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the Part D sponsor for the drug.

Effects

In performing the year-end reconciliation, CMS calculates a plan's risk corridor payment by subtracting any DIR received. If DIR is understated, and CMS's controls fail to detect the understatement, a plan's risk corridor payment would be overstated and the plan sponsor could receive a larger year-end payment from CMS than to which it was entitled.

Recommendations

We recommend that:

- (i) CMS applies more narrow thresholds and continues to refine its benchmarks and metrics for its DIR analysis. CMS should also consider including DIR metrics at the individual drug level and perform comparisons between plans at the drug level. Due to the nature of DIR reporting, CMS may be limited in drawing direct conclusions from DIR analysis; however, the results could be used by CMS as a risk factor in selecting plans for audit or other oversight activities. CMS should, where needed, coordinate and work with the OIG to align DIR oversight activities and further explore ways to incorporate PBM records in OIG or CMS oversight activities. CMS should obtain clarification from its Office of General Counsel to determine its authority to require PBMs to submit rebate data to CMS and for CMS to collect drug rebate data at the individual drug level to execute its responsibilities for DIR under the MMA.
- (ii) CMS requires plan sponsors to "true-up" reported annual estimated DIR amounts with actual amounts by plan and drug to allow a better basis for trending subsequent quarterly and annual submissions.

Management Response

CMS concurred with some recommendations and did not concur with others. CMS partially concurred with recommendation (i) and (ii). CMS did not concur with our recommendation to use DIR information obtained directly from PBMs to validate DIR reports submitted by plan sponsors since many plan sponsors rely on PBMs to prepare this information and because CMS's authority to request this information is unknown. CMS also noted that it may not be able to ensure access to PBM records.

Auditor's Comments

In response to CMS's comments, we revised the wording of recommendations (i) and (ii). We encourage CMS to obtain clarification on its authority with respect to PBMs since information obtained from a third party could provide an important source of corroboration.

4. CMS Should Conduct More Plan Sponsor Audit Procedures Throughout the Benefit Year (OARS 09-04)

Conditions

The CMS OFM performs audits of plan sponsors to help ensure that plan sponsors correctly administer the Part D benefits and that plan sponsor reported data to CMS is complete and accurate. Additionally, CMS CPC conducts operational audits throughout the benefit year. Those audits focus on plan sponsor procedural compliance with selected chapters of the Part D Manual. CPC also performs Risk Adjustment Data Validation (RADV) audits for Medicare Advantage plans and validates the mathematical accuracy of the RAF calculations. We performed procedures to determine the design and effectiveness of CMS's audit activities and determined that:

- (i) CMS does not perform audit activities throughout the current benefit year that focus on financial data that is key to year-end reconciliation, such as PDE records, DIR reporting and TrOOP accumulation. By design, OFM's audit activities start after year-end reconciliation is complete. OFM audits are intended to satisfy MMA audit requirements but are not an effective control to timely detect inaccuracies in PDE, TrOOP and DIR.
- (ii) CMS has not formally taken compliance action on audit results in a timely manner. The first compliance letters to plan sponsors based on OFM audit results of 2006 data were not sent out by CPC until September 2009. OFM informs CPC of audit progress and results. CPC is responsible for taking compliance action where needed. For 2006, 229 organizations had a total of 495 Part D contracts with CMS. For 2007, 255 organizations had a total of 572 Part D contracts with CMS. As of October 14, 2009, CMS had completed 100 out of 169 planned contract audits for 2006 and 19 out of 200 planned contract contracts for 2007. Audits for the 2008 plan year had not yet been started. In addition, CMS has sought ways to be more efficient and has reduced audit coverage for efficiency by auditing 86 of the same contracts for 2006 and 2007.
- (iii) The Medicare Enrollment Database (EDB) extract used by the Risk Adjustment System (RAS) contractor to calculate RAFs and the EDB extract used by the validation contractor to validate the RAF calculations are not created at the same time. This results in timing differences between the two sets of data making the identification and analysis of discrepancies more difficult.

Causes

- (i) Although CMS performs a number of plan sponsor oversight activities, to reduce overlapping responsibilities only OFM conducts audits that validate cost data submitted by plan sponsors. These audits are designed to meet legislative requirements and are performed after year-end reconciliation.

- (ii) The MMA requires CMS to conduct audits of one-third of Part D plan sponsors every year. However, the need to set up an audit infrastructure program, delayed start to performing audits, the time-intensive audit reporting process, and funding constraints have collectively challenged CMS's ability to perform the necessary audits and take corrective action in a timely manner.
- (iii) The EDB database extract is not pulled at the same time for the calculation of the RAF and the validation of the RAF because CMS deems the timing differences between the data extracts to be inconsequential.

Criteria

- (i) 42 CFR Part §423.504 states the requirements for one-third audits of plan sponsors: (d) Protection against fraud and beneficiary protections. (1) CMS annually audits the financial records (including but not limited to, data relating to Medicare utilization and costs, including allowable reinsurance and risk corridor costs as well as low-income subsidies and other costs) under this part of at least one-third of the Part D sponsors offering Part D drug plans.
- (ii) 42 CFR §423.104 establishes that periodic audits may be conducted: (4) Audits. CMS and the Office of the Inspector General may conduct periodic audits of the financial statements and all records of Part D sponsors pertaining to any qualified prescription drug coverage they may offer under a Part D plan.
- (iii) 42 CFR §423.329 requires that CMS establish an appropriate methodology for adjusting the standardized bid amount to take into account variation in costs for basic prescription drug coverage among Part D plans based on the differences in actuarial risk of different enrollees being served. Any risk adjustment is designed in a manner so as to be budget neutral in the aggregate to the risk of the Part D eligible individuals who enroll in Part D plans.

Effects

- (i) Because CMS completes audits of plan sponsors long after the end of a plan year and the year-end reconciliation, audit results do not impact the year-end reconciliation or payments to plans. Additionally, CMS is unable to provide timely oversight and communications with plans to help ensure compliance with CMS requirements. The timing lag on the benefit year (BY) 2006 and BY 2007 audits is continuing to affect the timeliness of the one-third audits, as BY 2008 audits have not yet been started.
- (ii) The delay in formally communicating audit results may delay corrective action by plan sponsor to avoid future errors.
- (iii) By not creating the EDB extract at the same time for both the RAF calculations and the RAF validation, CMS is reducing the precision of the RAF validation and is making it less likely that CMS will be able to determine if smaller differences between the RAFs calculated by the RAS contractor and the recalculated RAFs represent calculation errors or are due to timing differences in the data. Therefore, the current validation process could fail to detect calculation errors that could impact payments to plan sponsors.

Recommendations

We recommend that:

- (i) CPC, OFM, and OACT jointly enhance the Part D assurance and compliance program. The program can consist of CMS audits and independently audited assertions provided by plan sponsors such as SAS 70 examinations. The CMS Part D assurance program should:
 - Fully fund CMS's obligations under the Medicare Modernization Act to conduct timely audits of one-third of Part D plan sponsors annually
 - Include continuous audit procedures designed to provide relevant results prior to year-end reconciliation including sampling of claims to support PDE records and TrOOP balances
 - Include audit procedures designed to allow results to be extrapolated to identify the financial impact of findings on the Part D program and year-end reconciliation
 - Use CMS's statutory authority to audit plans to design tests of controls over systems and processes operated by service organizations (i.e., pharmacy benefit managers, claims processors, and enrollment service providers) that allow results to be leveraged across plan sponsors to reduce duplicative procedures and effectively deploy audit resources.
- (ii) CMS structure audits in a way to allow audit findings for discreet areas to be finalized more quickly and compliance action to be taken more promptly.
- (iii) CMS create the EDB extract at the same time for both the RAF calculation and the RAF validation, so timing differences in the data can no longer be used to explain smaller differences between the RAFs calculated by the RAS contractor and the RAFs recalculated by the validation contractor.

Management Response

CMS concurred with some recommendations and did not concur with others. CMS concurred with recommendations (i) and (ii). CMS did not concur with our recommendation for reinstating RADV audits for Part D Medicare Advantage. CMS also disagreed with recommendation (iii) to create an extract of the Medicare Enrollment Database at the same time for both the RAF calculation and the RAF validation to avoid discrepancies due to timing differences.

Auditor's Comments

In response to CMS's comments, we removed one recommendation that CMS did not concur with and agree with CMS's position on this matter as stated on page 10 of CMS's response, attached as Appendix C. We do not agree with CMS's response to recommendation (iii). We are not recommending additional audit procedures over the validation process. We also understand that despite the fact that the extracts are pulled at different times, the variance is inconsequential. We still recommend, however, that the production and validation contractors receive the same EDB extract so that discrepancies attributed to a difference in the point of time that the two extracts were run can be eliminated.

CONCLUSION

Based on our procedures, we noted that CMS has designed a layered compliance framework that uses as inputs beneficiary reported complaints, internal data analysis results, audits, and other continuous oversight activities to take compliance action against plan sponsors where needed. In addition, we understand that the current Part D program design disadvantages CMS from an internal control perspective as critical data needed for year-end

reconciliation, including PDE records and DIR information, is self-reported by plan sponsors. In addition, CMS is limited in its ability to react to plan sponsor bid audit results due to the program's complexity and statutory framework. Furthermore, while CMS performs statutorily mandated audits of one-third of plan sponsors for each year, these reviews do not provide for timely assessment of the accuracy and validity of plan sponsor reported information. CMS should do more to close the inherent internal control disparity that exists in the program. As such, we encourage CMS to implement more near-real-time auditing and monitoring controls, seek opportunities to expand access to and the use of point-of-sale information, and improve DIR reporting and auditing to the extent possible.

APPENDIX A – PROCESS FLOW DESCRIPTION

To fulfill the U.S. government’s obligation to the Part D program, CMS makes payments to private health insurance companies (plan sponsors) on a monthly basis through estimated subsidy payments and, where needed, at year-end as a result of the payment reconciliation process. Plan sponsors submit bids annually to CMS to participate in the Part D program. These bids outline the pricing and benefits for the plans the plan sponsor will offer and form the initial basis for determining monthly subsidy payments to the plan sponsor. The reconciliation process compares subsidy payments made to plan sponsors throughout the year with the cost data submitted by plan sponsors through PDE records and DIR reporting to determine any residual payments required by CMS to plan sponsors or plan sponsors to CMS. The reconciliation process relies on four major data sources: the sum of payments made to plan sponsors throughout the year, final updated plan enrollment, PDE records from plan sponsors and DIR reporting. These inputs into the reconciliation process are further discussed in the sections below.

Payments to Plan Sponsors

Using detailed beneficiary information submitted by plan sponsors with enrollment data and regional information about health care costs, CMS calculates estimated or predictive costs on a monthly basis. These monthly payments include a direct subsidy, a LIS and a reinsurance subsidy. After year-end reconciliation, CMS makes, where needed, a risk corridor payment. All three monthly payment types are calculated at the beneficiary level and aggregated to the plan level. These payment types are described in the following paragraphs.

Direct Subsidy – A plan sponsor’s direct subsidy payment is calculated per enrolled member by multiplying the plan sponsor’s standardized bid amount by the member’s RAF. The standardized bid amount equals the total covered drug cost multiplied by the percentage of defined standard benefit. The bid process is further explained in the *Plan Sponsor Bids* section below. The purpose of the RAF is to pay plan sponsors accurately by adjusting payments based on the expected prescription drug expenditures of their Medicare-enrolled population based on demographics and health status of that population. RAFs are calculated three times per coverage year for each enrollee. The first calculation is performed in the fourth quarter of the previous calendar year. A mid-year adjustment is calculated three months into the payment year using updated enrollment and diagnosis data. Based on the recalculated RAFs, adjustments are made to direct subsidy payments both prospectively and retroactively (back to January). The final RAFs are calculated four months after year-end using final enrollment data and are applied in July/August of that year. See the section *Risk Adjustment Factor* for more detail on how the RAFs are calculated.

Low-Income Cost-Sharing Subsidy (LICS) – The LICS payment is paid to the plan sponsor per qualifying enrollee based on the beneficiary’s income and asset levels. LICS payments are made to plan sponsors to cover the prospective LICS provided to qualified members at the point of sale. On a monthly basis, LICS payments are determined using an estimated cost per qualifying LIS enrollee. Estimated costs are determined using Medicare Beneficiary Database codes per LIS enrollee to determine the approximate amount of LIS Beneficiary Cost Sharing. The MMA deems the following categories of Medicare-eligible beneficiaries to be eligible for the LIS:

- Beneficiaries who are enrolled in Medicaid
- Beneficiaries who are deemed LIS eligible by SSA and are issued an Award letter by SSA
- Beneficiaries who receive SSI payments from SSA.

For each of the above categories of beneficiaries, there is a corresponding stream of data uploads that come from State Medicare agencies or from the SSA to CMS systems. For Medicare-eligible beneficiaries who are enrolled

in Medicaid (i.e., “dual eligibles”), CMS receives at least monthly Medicaid enrollment status uploads for the entire dual-eligible population from the States. For Medicare-eligible beneficiaries deemed LIS eligible by SSA or who receive SSI payments, CMS receives daily and weekly uploads of LIS award transactions or SSI recipient records from the SSA.

Reinsurance Subsidy – The purpose of the third payment type, Reinsurance Subsidy, is to reduce the risk for plan sponsors participating in Part D by guaranteeing them a certain amount of payment for beneficiaries with high drug costs. The Reinsurance subsidy is defined as a federal subsidy that covers 80 percent of allowable drug costs above the out-of-pocket threshold, net of DIR. The out-of-pocket (OOP) threshold is reached when the beneficiary accumulates a defined amount in TrOOP expenses in one coverage year (\$4,350 for the 2009 benefit year). TrOOP payments include all payments made on behalf of the beneficiary, or by specified third parties (including LICS payments.)

Risk Corridor Payment – The first three types of subsidy payments (i.e., Direct, Low Income, and Reinsurance) are paid monthly by CMS and reconciled at year-end. The fourth type of payment, the Risk Corridor Payment, is only paid to plan sponsors after the year-end reconciliation. This payment is also known as risk sharing, because it compares the payments made to plan sponsors throughout the year to the costs reported on PDEs that the payments are designed to cover. In this comparison, CMS uses the allowable cost (net of administrative cost) in both the initial coverage period and the catastrophic phase of the benefit and subtracts from the total payments the reinsurance subsidy that CMS pays. There is a target amount for the plan sponsor to reach, and any costs above or below this target amount are shared with the government in predefined symmetrical risk corridors. Therefore, the Risk Corridor Reconciliation can be positive, negative, or zero depending on the risk corridor that a plan sponsor falls in surrounding the target amount. The purpose of this payment is to limit a plan sponsor’s exposure to unexpected expenses not already included in the reinsurance subsidy or accounted for in the risk adjustment factors. The determination of the risk corridor payment is discussed in more detail in the Year-End Reconciliation section below.

Risk Adjustment Factor – The RAF is a multiplier used when calculating direct subsidy payments to help predict the costs of a beneficiary based on demographics, health status, and expected Medicare costs. Diagnosis data from Medicare Advantage Plans and Fee-for-Service (FFS) Plans is combined with beneficiaries’ demographic data from the Medicare Beneficiary Database (MBD) to calculate a RAF for each beneficiary. In addition to auditing the diagnosis data that drives the calculation of RAFs, CMS also validates the mathematical accuracy of the RAF calculations by having a validation contractor recalculate RAFs to compare with the RAFs calculated by the RAS contractor. After all validation and certification steps are performed, the RAF file is used to calculate the direct subsidy payments paid to plan sponsors.

Monthly Payment Validation – The CMS CPC validates that the monthly payments to each plan sponsor are correctly calculated by using two processes, the Plan Payment Validation (PPV) process and the Beneficiary Payment Validation (BPV) process. During the PPV process, CPC validates the common accounting numbers (CANs) used to code the payment transactions, validates that only active plans receive payments, and validates the completeness of data transfer from the Medicare Advantage Prescription Drug System (MARx), which calculates payments, to the Automated Plan Payment System (APPS) from which payments are executed. The purpose of the PPV validation process is to ensure that MARx correctly calculates the monthly plan payments at the beneficiary level. CPC compares the demographic and risk attributes of beneficiary data in MARx to the risk-adjustment factors and the MBD. CPC recalculates payments for every beneficiary using the MARx Monthly Membership Report (MMR), and for a 3 percent sample, CPC recalculates payments using source data from MBD, HPMS, and RAF files. CPC also reviews payment adjustments by plan type.

Prescription Drug Event Data

A PDE record is created every time a Medicare Part D beneficiary (i.e., an individual enrolled in a qualified Part D plan) fills a prescription covered under Part D. The PDE record is a summary record of all the transactions that occurred surrounding the dispensing event. Specifically, the PDE record lists the drug costs above and below the OOP threshold, separates basic prescription drug coverage benefits from enhanced benefits and includes all payments made at the point of sale. The plan sponsor is responsible for creating the record, maintaining an audit trail of PDE source data, and electronically submitting information to CMS.

A PDE record consists of 39 data fields. PDE records contain actual costs incurred by beneficiaries at the point of sale. PDE records include separate payment fields to distinguish between payments made by plans and payments made by beneficiaries or by others on behalf of beneficiaries. Both TrOOP-eligible and non-TrOOP-eligible payments are reported on PDE records. Plan sponsors are responsible for maintaining a beneficiary's TrOOP and drug spend balances, which the plan sponsors use to determine when the beneficiary will enter the coverage gap or reinsurance phases of the Part D benefit. To facilitate the complete and accurate accumulation of TrOOP balances, CMS has contracted with a third party to act as the TrOOP Facilitator. The TrOOP Facilitator sends plan sponsors data to inform plan sponsors of secondary payments on a Part D claim, so that when such secondary payments are not TrOOP eligible, plan sponsors can reduce the amount of TrOOP accumulated for the affected claims. The TrOOP Facilitator also sends data to plan sponsors to facilitate the transfer of TrOOP and drug spend balances between plan sponsors when a beneficiary changes his enrollment mid-year to a different plan sponsor.

Plan sponsors submit PDE records to CMS through the Prescription Drug Front End System (PDFS), from which an automated process transfers PDE records to the DDPS for various edit checks. In addition to performing up-front edit checks, the CPC conducts outlier analysis on PDE data in DDPS at the PDE and beneficiary level. CPC uses monthly reports produced by DDPS to identify significant outliers at the beneficiary level such as very high or negative financial fields. If an outlier is found, the Division of Payment Services (DPS) works with the Plan Compliance Officer to resolve any findings.

On a monthly basis, DDPS runs a Plan-to-Plan (P2P) Reconciliation process. A P2P Reconciliation is needed when one plan sponsor paid for Part D drugs in good faith on behalf of another plan sponsor because a beneficiary's plan enrollment was not updated or accurate. Plan sponsors have 30 days after the effective date of a beneficiary's new coverage, or 30 days after the date the new contract of record submits the enrollment to CMS, to submit P2P PDE data. The submitting plan sponsor will send the PDE data for the affected claims to PDFS. DDPS reassigns the PDE costs to the contract of record for final reconciliation. DDPS issues monthly reports to plan sponsors under the P2P processes. These reports include monthly receivables and payables for plan sponsors and the reconciliation payment. CPC validates these payments and a CMS contractor distributes the reports to plan sponsors. The contract of record will then pay the submitting contractor.

Once DDPS has performed edit checks, the PDE records are forwarded to the Integrated Data Repository (IDR). The IDR stores PDE records and accumulates summary data used in payment reconciliation. The IDR sums LICS amounts, gross drug costs above and below out-of-pocket threshold, and covered D plan-paid amounts. This data feeds directly into the Payment Reconciliation System (PRS), which creates a record for each beneficiary enrolled in the plan during the fiscal year and calculates reconciliation payments at the plan level.

Direct and Indirect Remuneration

DIR refers to discounts, rebates, and other price concessions from manufacturers or Pharmacy Benefit Managers on drugs that lower the plan sponsor's net drug costs. In performing the year-end reconciliation, CMS calculates a plan's allowable risk corridor costs by subtracting DIR received by plan sponsor. Plans report DIR to CMS once per year before the year-end reconciliation. CMS performs an analysis of DIR data based on 13 assumptions in an attempt to validate the reasonableness of each plan's reported DIR.

Final Part D Plan Enrollment Data

Part D plan sponsors must submit all complete enrollment requests to CMS, so the beneficiary can be recorded as an enrollee with the Part D plan sponsor. Effective in 2008, plan sponsors have seven calendar days to submit enrollment data to CMS after the complete enrollment request is received. Plan sponsors submit enrollment data to CMS through the MARx system. MARx accesses the MBD and the SSA's Master Beneficiary Record (MBR) system to confirm the status of beneficiaries. At the end of the fiscal year, a final update is made to plan enrollment. Plan sponsors are responsible for submitting updated enrollment information which may reflect changes in enrollment dates, LIC subsidy status, retroactive changes, etc. CMS uses enrollment data to calculate the final RAFs for the year. This information is used in the Risk Adjustment Reconciliation Process to calculate the Direct Subsidy Reconciliation.

Year-end Reconciliation

Payment reconciliation begins with the Risk Adjustment Reconciliation. This process uses year-end RAFs to recalculate the monthly prospective risk adjusted direct subsidy payments. These amounts are reconciled with the actual payments that were made to plan sponsors during the year. The Risk Adjustment Reconciliation process takes place in MARx and these payments are issued separately from the LICS, reinsurance, and risk corridor reconciliations. The reconciliation of the LICS payments is straightforward, because there is a dollar-for-dollar reconciliation with what was paid to plan sponsors and what was submitted on PDE records. Plan sponsors are either billed or reimbursed based on reconciliation.

The Reinsurance Reconciliation is the next reconciliation processed. CMS compares the monthly prospective reinsurance payments made to the plan sponsor to the actual reinsurance subsidy due to the plan sponsor according to costs reinsurer for Part D, covering 80 percent of covered Part D drugs above the out-of-pocket threshold, net of administrative costs and DIR.

The final reconciliation calculated is the Risk Corridor Reconciliation. This payment is also known as risk sharing, because it compares the payments made to plan sponsors throughout the year, net of administrative costs, to the costs reported on PDE's that the payments are designed to cover. There is a target amount for the plan sponsor to reach, and any costs above or below this target amount are shared with the government in predefined symmetrical risk corridors. Therefore, the Risk Corridor Reconciliation can be positive, negative, or zero depending on the risk corridor that a plan sponsor falls in surrounding the target amount. CMS calculates a target amount for each plan by totaling Direct Subsidy payments and monthly premiums paid to the plan and discounting the total payments by an administrative costs ratio. CMS then calculates the plan's allowable costs from the initial coverage phase of the benefit by totaling covered Part D drug costs recorded on PDE records and subtracting both DIR and Part D drug costs from the reinsurance (i.e., catastrophic) phase of the benefit. CMS refers to the resulting total as Adjusted Allowable Risk Corridor Costs (AARCC). For each plan, CMS compares the AARCC to the target amount. When the AARCC is less than the target amount, the difference (i.e., excess payments) is retained by the plan as profit down to a certain risk corridor threshold, after which part of the difference is refunded by the plan to CMS. When the AARCC exceeds the target amount, the difference (i.e., excess costs) is absorbed by the plan as a loss up to a certain risk corridor threshold, after which part of the difference is reimbursed to the plan by CMS.

The reconciliation of the payment types discussed above is summarized in Figure 1 below. The figure shows the data elements used to determine the final actual costs for each payment type and the data elements used to calculate the total payments made to the plan sponsors through the year. The cost and payment data are compared to determine any amounts due or owed. The risk corridor payment is determined after the three subsidy payments are reconciled and the figure shows the relevant data elements that serve as inputs to risk corridor payment determination.

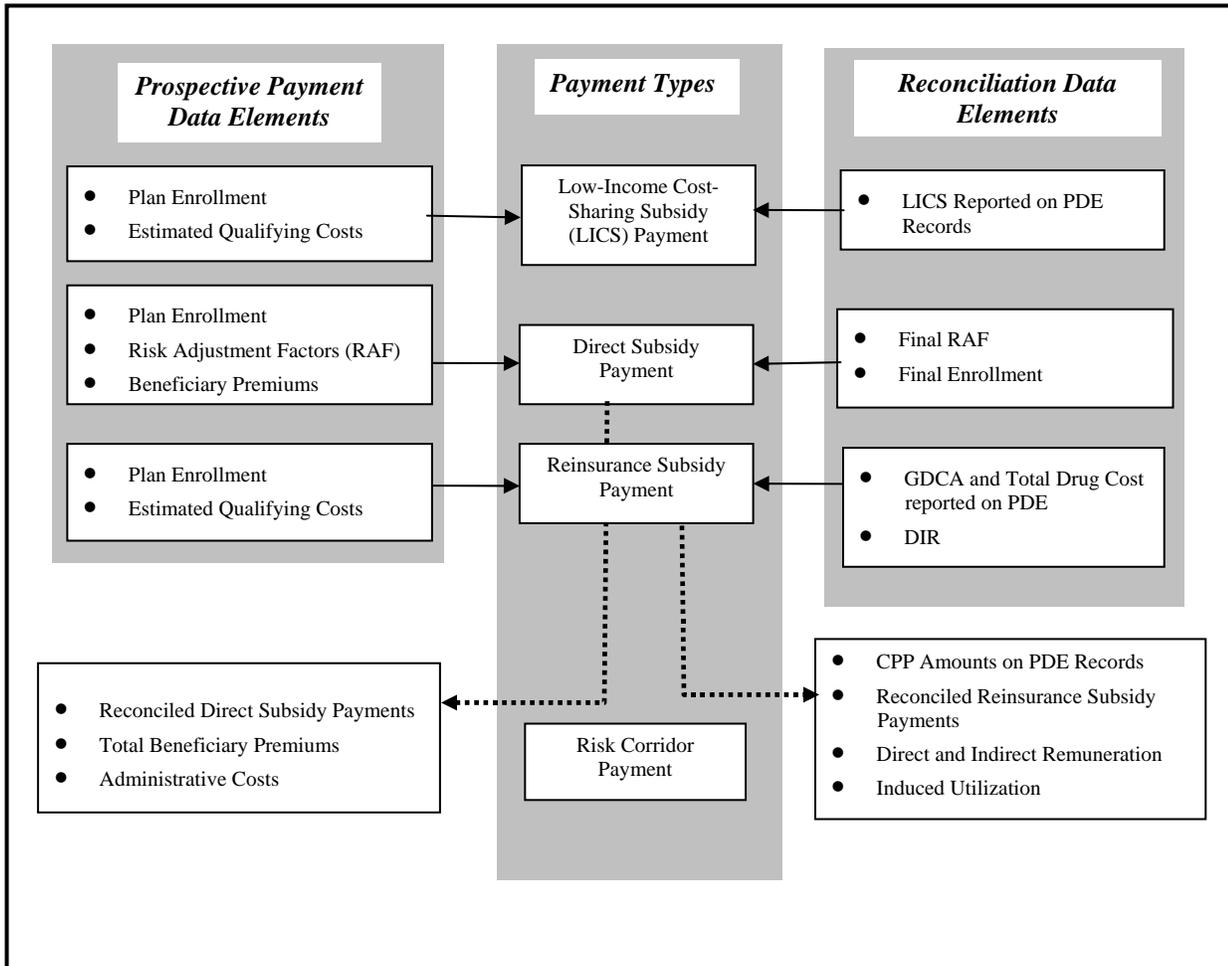


Figure 1 – Overview of prospective payment and reconciliation data elements

After all of the payment reconciliation calculations have been performed, the PRS generates validation reports and the CPC reviews the reconciliations to validate results. Additionally, CPC independently validates inputs and outputs of PRS using the Reconciliation Input Report and Reconciliation Output Report. The Reconciliation Input Report shows annual plan sponsor input data for LICS and Reinsurance reconciliations. The Reconciliation Results Report shows all PRS inputs, calculations, and reconciliation results at the plan level and rolled up to the contract and program levels. Once reconciliation data has been confirmed, it is transferred to the Automated Plan Payment System (APPS) for payment. All payments are validated and authorized by the Medicare Plan Payment Group (MPPG).

APPENDIX B – ACRONYMS

Adjusted Allowable Risk Corridor Costs	AARCC
Center for Drug and Health Plan Choice	CPC
Centers for Medicare and Medicaid	CMS
Covered D Plan Paid Amount	CPP
Direct and Indirect Remuneration	DIR
Drug Data Processing System	DDPS
Gross Drug Cost Above the Out-of-Pocket Threshold	GDCA
Gross Drug Cost Below the Out-of-Pocket Threshold	GDCB
Health Plan Management System	HPMS
KPMG LLP	KPMG
Low-Income Cost-Sharing Subsidy	LICS
Low-Income Subsidy	LIS
Medicare Advantage Prescription Drug System	MARx
Medicare Beneficiary Database	MBD
Medicare Enrollment Database	EDB
Medicare Modernization Act	MMA
Objective Attribute Recap Sheet	OARS
Office of the Actuary	OACT
Office of Financial Management	OFM
Office of the Inspector General	OIG
Out of Pocket	OOP
Plan-to-Plan	P2P
Plan Payment Validation	PPV
Prescription Drug Event	PDE
Risk Adjustment Data Validation	RADV
Risk Adjustment Factor	RAF

Risk Adjustment System	RAS
Social Security Administration	SSA
Supplemental Security Income	SSI
True-Out-of-Pocket	TrOOP

APPENDIX C – MANAGEMENT RESPONSE



Administrator
Washington, DC 20201

DATE: **MAK 11 2010**

TO: Daniel R. Levinson
 Inspector General

FROM: *Charlene Frizzera*
 Charlene Frizzera
 Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Part D - Prescription Drug Event Reconciliation Process" (A-18-08-30102)

The Centers for Medicare & Medicaid Services (CMS) appreciates the OIG's work with respect to the Medicare Part D Prescription Drug Event (PDE) reconciliation process. The OIG, through its contractor KPMG, LLP, audited the Part D payment system to determine whether CMS controls overpayments to plan sponsors, PDE records, and year-end reconciliation provided reasonable assurance that:

- 1) The inputs that drive the calculation of monthly payments are accurate and complete;
- 2) The Risk Adjustment Factor calculations by the Risk Adjustment Processing System (RAPS) are accurate;
- 3) Monthly payments are accurately calculated and tracked;
- 4) Submitted PDE records are valid, accurate, and complete;
- 5) PDE data are complete before year-end reconciliation; and
- 6) Direct or indirect remuneration (DIR) reporting is accurate and complete.

KPMG made findings and recommendations for improvement. Attached is a listing of those findings and recommendations and CMS' responses. Also included in the attachment are technical comments.

The CMS looks forward to continuing to work with the OIG to strengthen the Medicare Part D Program. Thank you for the opportunity to comment on this draft report.

ATTACHMENT

• **KPMG FINDING: CMS Should Strengthen Controls Over the Bid Review and Audit Process.**

CMS Response to Finding:

The CMS concurs with this finding.

KPMG Recommendation:

Prior to approving the bid, CMS continues to ensure that the bid reviews and sub-reviews are documented as complete and that the review results support the recommendation to approve the bid.

CMS Response:

The CMS concurs with this recommendation.

To put the findings for the bid desk review for contract year 2009 in perspective, OIG reviewed a total of 560 sub-reviews (14 sub-reviews for each of the 40 Part D bids selected for audit), and identified a single sub-review where the documentation in the Health Plan Management System (HPMS) did not provide adequate support for completion. KPMG only found evidence that 1 of 560 sub-reviews was not documented, not that the review was not completed.

Subsequent to the review of the 2009 bids, CMS enhanced the 2010 bid desk review to improve controls even further by requiring documentation and approval for every sub-review, even when that sub-review is not required for approval of a particular bid. The two exceptions are: (1) the "other" sub-review is only used at the direction of CMS' Office of the Actuary (OACT) and was not utilized for contract year 2010, (2) the "reviewer sign-off" sub-review is not required to be completed by OACT's Bid Desk Review Manual, because contracted reviewer sign-off is only required at the contractor level. It is permissible for these two sub-reviews to remain in a "not started" status at completion of the bid desk review; however, it is not permissible for the two sub-reviews to have a status of "in-progress." This enhancement was implemented in the 2010 bid desk review process, and CMS expects it to further reduce the likelihood that a sub-review will not be completely documented.

KPMG Recommendation:

The CMS should consider implementing automated edits and reporting in HPMS, which could aid in ensuring each required bid sub-review is recorded as complete prior to allowing CMS to document approval of the bid.

CMS Response:

The CMS does not concur with this recommendation. HPMS is the system that is used to document the results of the bid review. The vast majority of bid review processing and controls are outside of the system. Pulling this control into the system moves the control further away from where the work is being performed, thus limiting the effectiveness of the control and efficiency of the process. As discussed in our response to the previous recommendation, CMS enhanced the 2010 bid desk review to improve controls by requiring documentation and approval for every sub-review, even when that sub-review is not required for approval of a particular bid. This enhancement was implemented in the 2010 bid desk review process, and CMS expects that it will ensure that all sub-reviews are completely documented.

KPMG Recommendation:

The CMS further review its options for adjusting payments to, or recovering overpayments from plan sponsors when bid audits find that bids have errors or omissions that resulted in avoidable overpayments.

CMS Response:

The CMS does not concur with this recommendation. Plan sponsors submit bids to CMS prior to a plan year. CMS reviews and, when appropriate, negotiates with plan sponsors to ensure that bids are submitted per CMS instructions and that bids are reasonable. What is ultimately owed to, or from, plan sponsors after the plan year closes depends upon the plan sponsor's experience during the year. Congress created the end-of-year reconciliation process specifically because it recognized the uncertainties involved in the prospective bidding process. CMS does not have the authority to adjust plan sponsors' bid amounts, payments to plan sponsors, or beneficiary premiums once a bid has been accepted. In fact, once the bid is accepted and used to set plan premiums and payment levels, there is no legal authority to revise the accepted bid amount for any purpose, including adjusting plan payments. Even if CMS had the authority to adjust a bid after it is accepted, doing so could result in a variety of unintended consequences, depending on whether the correction of an error in a bid would result in avoidable under- or overpayments for the plan. For example, changing a plan's bid would require retroactively changing the premium under the Part D rules in that plan. If the bid is revised at the end of a plan year, then all premiums may be revised throughout the plan year. This means that the beneficiary would receive a bill from the plan sponsor for the difference in premiums, if the premium went up after revision. As noted in KPMG's draft report, due to Part D requirements relating to premium calculation, changing one plan's bid also has the potential to affect premiums charged to all Part D beneficiaries. Such a structure would be contrary to CMS' goals of promoting a benefit that establishes beneficiary protection and certainty, and program stability.

The statute provides a framework for how discrepancies between plan sponsors' bids and costs should be reconciled, including specific requirements on the extent to which the Government and plan sponsors assume risk. CMS has accurately followed the reconciliation requirements in the statute.

KPMG Recommendation:

The CMS require individual actuaries to certify their independence of the plan sponsor prior to performing bid reviews or bid audits.

CMS Response:

The CMS agrees with KPMG that individual actuaries must be independent of the plan sponsor when conducting bid reviews and bid audits to avoid an actual or perceived bias when reviewing and auditing bids. CMS feels that it is of the utmost importance to ensure that conflicts of interest do not influence the bid review and bid audit process, and CMS believes that its current procedures for identifying and addressing conflicts of interest with bid desk review and bid audit contractors are sufficient to eliminate motive for manipulating review and audit findings. CMS currently uses the following procedures for identifying and addressing conflicts of interest with its bid desk review and bid audit contractors:

- 1) Each contractor must submit a list of potential conflicts of interest with its proposal for services (included in its Technical Proposal sent to CMS' contracting department – the Office of Acquisitions and Grants Management (OAGM)). Conflicts are separated into: a) any association or business arrangement with a Medicare Advantage or Prescription Drug plan during the past 12 months, and b) any involvement in the preparation of the bids to be reviewed or audited. This proposal information is retained and maintained by OAGM.
- 2) At the time that bid reviews or bid audits are assigned to contractors, CMS avoids conflicts identified in item 1 above. CMS' OACT also submits a preliminary assignment list (by email) to each contractor. The contractor must reply whether or not it has any potential conflicts of interest with the preliminary assignments and elaborate on the reason, as necessary. The contractors' responses are used to adjust and finalize the assignments as necessary. This process may require several iterations, as bids must be reassigned and additional conflict checks must be made during each iteration. A record of this process is maintained through email correspondence between OACT and the contractors.
- 3) The CMS also checks and avoids the assignment of any bids to the contractors in which the contractor was the certifying actuary for a bid.
- 4) If at any time during the reviews or audits a conflict is identified by CMS or the contractor, CMS will reassign the bids, as necessary. A record of this process is maintained through email correspondence between CMS and the contractor.

While CMS believes that its current process as outlined above assures that individual actuaries must be independent of the plan sponsor when conducting bid reviews and bid audits, CMS will consider adding a duplicative requirement to have individual actuaries certify their independence of the plan sponsor prior to performing bid reviews or bid audits in our future work.

KPMG Recommendation:

The CMS formalize a peer review approach for bid audits where a selection of bids audits are performed by an actuarial firm that did not perform the bid review, and document this additional quality control in its internal control documentation.

CMS Response:

The CMS does not concur with this recommendation. This recommendation would reduce the efficiency and/or the efficacy of the bid audit. The bid audit is not an evaluation of the work completed by the bid desk reviewer during the bid desk review, and CMS does not use a finding from the bid audit to evaluate the performance of a contractor in the bid desk review. It is important to note that the bid audits evaluate specified aspects of the bid independent of the outcome of the earlier bid desk review, and because the scope, considerations, and approach to the reviews and audits are different, CMS does not consider it to be a contradiction for the bid audit to identify an issue that passed the bid desk review. This position is communicated to the contractors at the start of the audit process.

In addition, because the work of the bid audit builds upon the experience in the bid desk review, any familiarity of the bid auditor with the issues previously covered in the bid desk review generally enhances the effectiveness of the audit. The bid audit is a more in-depth evaluation of the bid relative to the bid desk reviews that is performed earlier in the year and is intended to identify issues that may not have been apparent or looked at during the bid desk review. CMS feels that it is of the utmost importance to ensure that conflicts of interest do not influence the bid review and bid audit process, and it believes that its current procedures for identifying and addressing conflicts of interest with bid desk review and bid audit contractors are sufficient to eliminate any motive for manipulating review and audit findings.

- **KPMG FINDING: Controls To Ensure The Accuracy and Completeness of PDE and TrOOP Accumulation Need Improvement.**

CMS Response to Finding:

The CMS agrees in part with KPMG's finding.

KPMG Recommendation:

The CMS develops and implements system-based edits to prevent and detect errors in the calculations of PDE payment and cost fields that are used in the year-end reconciliation such as Covered D Plan Paid Amount (CPP), Gross Drug Cost Below out-of-pocket threshold (GDCB) and Gross Drug Cost Above out-of-pocket threshold (GDCA). CMS should consider interim steps such as: Adding fields to the PDE record lay-out for plans to report drug spend and true out-of-pocket (TrOOP) accumulator balances on every PDE record, and thereby using plan sponsor reported accumulator balances as the basis for detective cost and payment field edits (i.e., CPP, GDCB, and GDCA).

CMS Response:

The CMS agrees in concept and is reviewing options introduced with D.0 (Jan 2012).

KPMG Recommendation:

Developing, outside of Drug Data Processing System (DDPS), an analysis mechanism to detect inaccurate payment and cost fields for a subset of PDE records based on CMS' recalculation of CPP, GDCB, and GDCA fields and independent accumulation of TrOOP and drug spend balances. As CMS refines the operation of such a detective control, it could then incrementally increase the volume of PDE records recalculated and ultimately implement real-time preventative payment and cost field edits.

CMS Response:

The CMS generally agrees. CMS expanded individual PDE outlier analysis in 2009 and also has a TrOOP balance validation study underway. The current priority is to finalize results and follow up with 2009 employer plans with insufficient TrOOP balances to substantiate catastrophic benefits. CMS agrees that there should be an analysis to detect inaccurate payment and cost fields for a subset of beneficiaries and PDE records based on CMS' recalculation of CPP, GDCB, and GDCA fields and independent accumulation of TrOOP and drug spend balances.

KPMG Recommendation:

The CMS studies the feasibility of obtaining and using point-of-sale data in the determination of monthly payments, to conduct near real-time validation of PDE records, and to anticipate year-end program costs. KPMG recommends that the study focus on the technical and programmatic aspects of real-time, point-of-sale data collection and determine the opportunities, limitations, and cost-benefits of enhancing automated controls over PDE record validation while considering current, mostly ad hoc, data validation processes. The study should consider the current Part D program design and propose near- and long-term solutions to help optimize Part D program real-time monitoring controls in a cost-effective manner.

CMS Response:

The CMS agrees with this recommendation. CMS can perform a study to review the feasibility of obtaining and using point-of-sale data in the determination of monthly payments, to conduct near real-time validation of PDE records, and to anticipate year-end program costs. CMS will review the extent of the benefits and limitations of obtaining and using point of sale data for these purposes. Due to potential legal and operational limitations, the threshold question will be whether CMS can obtain this data in a cost effective and timely manner. If this data cannot be obtained in such a manner, studying the use of the data will become a moot issue.

KPMG Recommendation:

The CMS implements a formal oversight program of the TrOOP Facilitator and continues to work with insurers to encourage the sharing of enrollee information and consider obtaining additional point-of-sale transaction information to allow comparison of the plan sponsor and pharmacy-reported information and anticipate the number of outstanding PDE records.

CMS Response:

The CMS partially concurs with the recommendation. We agree with the recommendation for a formal oversight program of the Facilitator and agree it should be implemented to ensure a sustained level of high performance. CMS also agrees that it should continue to encourage other providers of prescription drug coverage to enter into data sharing agreements with CMS. Such agreements may enable CMS to provide more complete information on beneficiaries' other drug coverage to Part D sponsors for coordination of benefit activities and to the TrOOP Facilitator for identification of point-of-sale claims transactions supplemental to Part D and for creation of Nx transactions. CMS notes that unless other insurers supplemental to Medicare establish unique identifiers (i.e., Rx BIN or Rx BIN/PCN combination) for each separate plan they offer, claims that are supplemental to Part D cannot be distinguished from all others. As a result, the TrOOP Facilitator's receipt of other payer claims information will not translate into the creation of additional Nx transactions, specifically if the additional claims cannot be matched with Part D beneficiaries. While we can encourage other payers to establish and use unique identifiers, CMS has no authority to require other insurers do so.

The CMS continues to work with the TrOOP Facilitator and the industry to encourage improvement of the Nx transaction process. Until process improvements are in place, CMS does not agree that Nx transactions should be compared to reported PDE data or used for estimating the number of outstanding PDEs.

KPMG Recommendation:

The CMS implements a control to monitor the weekly uploads from the SSA of SSI eligibility data to detect and correct any errors that require manual intervention to be resolved.

CMS Response:

The CMS agrees that the monitoring of weekly data from Social Security Administration (SSA) of Supplemental Security Income (SSI) eligibility files is a necessary step to detect and resolve errors. While not a formalized process, a daily report is provided that contains the number of records received from SSA. On a separate track, CMS receives a report of the errors that were generated in association with processing the SSA file. In addition to the regular reporting, CMS meets regularly with SSA to address system fixes and errors generated by these files. There have been extensive cleanups of error files in addition to a number of software fixes implemented in order to have more efficient processing of the file exchanges between the two agencies. This workgroup is ongoing and will continue as long as there is a need to address this issue. At present the error rate is less than 1 percent.

- **KPMG FINDING: CMS Should Enhance Controls To Ensure Completeness and Accuracy of DIR Prior to Reconciliation.**

CMS Response to Finding:

The CMS agrees in part.

KPMG Recommendation:

The CMS establish benchmarks and metrics to facilitate DIR Analysis at the individual drug level and comparisons between plans at the drug level. We also recommend that plans be required to “true-up” reported annual estimated DIR amounts with actual amounts by plan and drug to allow a better basis for trending subsequent quarterly and annual submissions. Due to the nature of DIR reporting, CMS may be limited in drawing direct conclusions from DIR analysis; however, the results could be used by CMS as a risk factor in selecting plans for audit or other oversight activities.

CMS Response:

The CMS agrees with this recommendation and will consider requiring Part D sponsors to submit revised DIR Reports with their actual DIR amounts for a “true-up” analysis. Please note that CMS currently uses the results of the DIR reasonableness reviews to aid in selecting plans for audit. In response to KPMG’s recommendation that CMS collect the DIR data at the individual drug level, CMS notes that to conduct Part D payment reconciliation, it is only necessary to collect DIR data at the plan level. Rebate data is considered proprietary by the industry, particularly at the individual drug level where the rebate level can be determined for a specific drug. It is unclear whether it is necessary to collect and analyze DIR data at this level to ensure that it is reasonable and complete. Furthermore, establishing benchmarks and metrics at the individual drug level may not be effective given the large variability in the level of rebates provided by pharmaceutical manufacturers to different sponsors.

KPMG Recommendation:

The CMS explore the possibility of receiving regular confirmations from manufacturers and Pharmacy Benefit Managers (PBMs) on DIR extended to plans or parent organizations. This may reduce the annual audit burden on PBMs and facilitate the more real-time monitoring of DIR data.

CMS Response:

The CMS does not agree with this recommendation. Many sponsors currently submit DIR reports that have been prepared by their PBMs. Therefore, using information collected directly from PBMs to validate the DIR reports would be limited in its effectiveness. Furthermore, it is questionable whether CMS has the authority to require pharmaceutical manufacturers to submit rebate data given that Part D contracts are with Part D sponsors and not pharmaceutical

manufacturers. Such a requirement may violate the non-interference provisions of the Social Security Act at Section 1860D-11(h)(i).

KPMG Recommendation:

The CMS accelerate its audits of plan sponsor DIR reporting, audit a larger selection of plans for DIR, and conduct comprehensive DIR audits by reconciling plan sponsor DIR records with those of PBMs. CMS should, where needed, coordinate and work with the OIG to align audit activities and ensure access to PBM records.

CMS Response:

The CMS agrees in part and disagrees in part. With respect to auditing a larger selection of plans, CMS agrees. Due to budget constraints in the past, CMS faced numerous challenges that caused delays in conducting the annual audits of the financial records of one-third of the Part D sponsors offering Part D drug plans. However, CMS is committed to increase audit efficiency and effectiveness by researching and implementing (if determined appropriate) new ideas and approaches. With respect to accelerating audits, it is most effective to audit plan sponsors after final reconciliation of a plan year, which does not occur until final PDEs, DIR, and TrOOP balances are submitted, which does not occur until midway through the year following the plan year. To accelerate audits would cause audits to be based in un-finalized data. With respect to reconciling DIR reports with PBMs, CMS disagrees with this recommendation. Many sponsors currently submit DIR reports that have been prepared by their PBMs. Therefore, using information collected directly from PBMs to validate the DIR reports would be limited in its effectiveness. CMS agrees that it should, where needed, coordinate and work with the OIG to align audit activities, but it does not agree that it can ensure access to PBM records.

• KPMG FINDING: CMS Should Conduct More Plan Sponsor Audit Procedures Throughout the Benefit Year.

CMS Response to Finding:

CMS agrees in part.

KPMG Recommendation:

The CMS' Center for Drug and Health Plan Choice (CPC), Office of Financial Management (OFM), and OACT jointly enhance the Part D assurance and compliance program. The program can consist of CMS audits and independently audited assertions provided by plan sponsors such as SAS 70 examinations.

CMS Response:

The CMS agrees with this recommendation. While the timing of the OFM financial audits is accurately characterized, the report failed to mention that the financial audits include a review of PDEs, DIR, and TrOOP used in the reconciliation. The reconciliation usually occurs 6 months

after the benefit year. Since plans are allowed to make various corrections to PDEs throughout the benefit year, OFM specifically performs the financial audits after the year-end reconciliation. This ensures a sample of the final PDEs used in the reconciliation is audited. All financial audit results are shared with OACT and CPC. As mentioned in the report, CMS has the authority to reopen reconciliation for good cause. This authority could be exercised to make adjustments based on the results of the financial audits.

The CMS will continue to increase audit efficiency and effectiveness by researching and implementing (if determined appropriate) new ideas and approaches such as those recommended by KPMG to include expanded extrapolation of audit results and compartmentalized audits.

KPMG Recommendation:

The CMS reinstate Risk Adjustment Data Validation (RADV) audits for Part D Medicare Advantage (MA) plans to the extent necessary for CMS to have visibility to assess the level of inaccurate diagnosis data and its affect on the calculation of risk factors and payments to Part D plan sponsors.

CMS Response:

The CMS does not agree with this recommendation. CMS discussed this topic with KPMG and made clear that risk adjustment in Part D does not have the same vulnerability as risk adjustment in Part C, and therefore Federal resources are better spent focusing on the Part C risk adjustment data. As explained, Medicare Advantage organizations (MAOs) submit risk adjustment data to CMS, on which CMS calculates risk scores. Under Part C, plan sponsors have an incentive to ensure that risk scores are as high as possible, because it increases plan payment. In order to ensure that MAOs are not up-coding, CMS must validate the information submitted. Part D risk scores are largely based on Medicare fee-for-service data and Part D risk scores have a smaller impact on final payment. Therefore it is prudent to focus on the Part C program with respect to risk adjustment data validation and not on the Part D program where the use of audit resources will be much less effective.

KPMG Recommendation:

The CMS create the Medicare Enrollment Database extract at the same time for both the Risk Adjustment Factor (RAF) calculation and the RAF validation, so timing differences in the data can no longer be used to explain smaller differences between the RAFs calculated by the Risk Adjustment System (RAS) contractor and the RAFs recalculated by the validation contractor.

CMS Response:

The CMS does not agree with this recommendation. CMS has extensive internal controls over this process as outlined in its validation standard operating procedures and verified by the A-123 contractors. There were no significant differences between the RAFs calculated by the RAS contractor and the RAFs recalculated by the validation contractor, which is approximately .005

percent in 2010, so to spend more funds and resources on auditing a process that currently works would not be the most prudent use of Government resources.

To synchronize the inputs of the production and validation contractors would negate the purpose of the validation contractor. If the validation contractor uses the same inputs from the same day, it will merely be performing a proforma function that serves little or no purpose because the validation contractor would merely be recreating the same risk scores as the production contractor with the same inputs, and ultimately the same outcomes regardless of any inaccuracies.

Technical Comments: CMS has several technical comments.

- 1) KPMG states the following on pages 2 and 25 of the draft report.

Time constraints and the rapid implementation schedule of the Part D Program (the Program) resulted in a departure from the original design of how Part D claims data would be adjudicated and reported to CMS.

There was no departure from the original design of how Part D claims data would be adjudicated and reported to CMS. Therefore, this statement should be removed from the final report, because it is incorrect.

- 2) CMS recommends changes in Figure 1 on page 8. First eliminate Plan-to-Plan on the Payment Side. Plan-to-Plan payments are coordination of benefit payments from the submitting contract (SC) to the Contract of Record (COR). Plan-to-plan reconciliation aligns cost with the COR and reimburses the SC. Just like benefit coordination from non-Part D payers, Plan-to-Plan payments to the SC are not a revenue source for reconciliation.

Several items should be moved from the cost side of the document to the payment side. The Low Income Cost Sharing (LICS) payment should include the LICS prospective payment which KPMG describes as “plan estimated costs indicated on their bid.” Similarly the Direct Subsidy, Beneficiary Premiums and the Reinsurance Subsidy should display on the payment side. They are another source of payment KPMG describes as “plan estimated costs indicated on their bid.” Finally, Direct and Indirect Remuneration should display on the payment side.

Although Direct and Indirect Remuneration is paid by manufacturers, not CMS, it is a payment that is used to reduce cost and should be reported as a payment side.

- 3) On page 10, KPMG incorrectly notes that there are 59 PDE data elements, when there are actually 39. KPMG may be confusing additional data the Office of Information Services includes on the TAP file with data that sponsors report on the PDE. CMS does not include additional data elements on the TAP file as PDE data elements.

- 4) In the outlier description on page 10, it should be clarified that CMS performs outlier analysis at both the PDE level and the beneficiary level. Monthly reports are the source data for beneficiary-level outlier analysis.

- 5) Modify the description of Risk Corridor Reconciliation beginning at the bottom of page 11. Risk-sharing is based on plan allowable cost in both the initial coverage period and the catastrophic phase of the benefit. CMS does not subtract Part D costs from reinsurance. CMS subtracts the reinsurance subsidy that CMS pays; otherwise CMS would duplicate payment.

- 6) On page 20 of the draft report, KPMG indicates that the DIR reasonableness reviews have a high level of tolerance for inaccurate or incomplete DIR reporting. CMS will consider applying more narrow thresholds as it continues to refine and develop the DIR reasonableness reviews. CMS notes that the DIR reasonableness reviews have a low tolerance for incomplete DIR data as all Part D sponsors that report no DIR are required to validate that they in fact

received no DIR and provide a justification. The thresholds used for the DIR reasonableness reviews give the appearance of a high level of tolerance for inaccurate reporting, because they reflect that the level of DIR received by Part D sponsors varies significantly. However, with these thresholds, over 70 percent of Part D contracts and 60 percent of Part D sponsors (including the 10 sponsors with the largest Part D enrollment) were flagged during the reasonableness reviews for the 2008 DIR data.

7) Also on page 20 of the draft report, KPMG implies that the findings from the financial audits suggest that DIR reporting is not reasonably complete and accurate. However, CMS notes that only a small number of Part D sponsors were found to have significantly under- or over-reported their DIR data. Of those Part D sponsors found to have inaccurately reported their DIR data, most over-reported their DIR data. Overall, the DIR amounts reported to CMS have been reasonably accurate. The number of cases where Part D sponsors have reported DIR greater than the DIR amounts actually received (i.e. over-reported their DIR data) suggests that Part D sponsors have been conservative in their DIR estimates. In such cases, their payments from the Federal Government have been lower than they would have been otherwise.