Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

TRACKING BENEFICIARIES' TRUE OUT-OF-POCKET COSTS FOR THE PART D PRESCRIPTION DRUG BENEFIT

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EXECUTIVE SUMMARY

OBJECTIVE

1. To review the processes that Part D plans and the Coordination of Benefits Contractor (COBC) use to help ensure the accurate tracking of beneficiaries' true out-of-pocket (TrOOP) costs.
2. To determine the extent to which the Centers for Medicare & Medicaid Services (CMS) conducts oversight of Part D plans to ensure the accurate tracking of TrOOP costs.

BACKGROUND

The Medicare prescription drug program, known as Medicare Part D, provides an optional prescription drug benefit for all Medicare beneficiaries. Part D plans are responsible for tracking beneficiaries' TrOOP costs. TrOOP costs are the prescription drug expenditures that count toward the annual out-of-pocket threshold that beneficiaries must reach before catastrophic drug coverage begins. Medicare beneficiaries enrolled in Part D plans may have additional prescription drug coverage. Tracking TrOOP costs involves coordination and communication between CMS, contractors such as COBC, Part D plans, and other payers of prescription drug benefits. The amount of beneficiaries' TrOOP costs impacts their cost sharing as well as CMS payments to Part D plans.

To review the processes for and CMS's oversight of the accurate tracking of beneficiaries' TrOOP costs, we interviewed staff from CMS and its contractors and analyzed survey information from a sample of 138 Part D plans regarding activities, policies, and procedures related to TrOOP costs. We gathered and analyzed relevant documentation from respondents. We collected data from October 2006 through March 2007.

FINDINGS

Information on enrollees' additional drug coverage, essential for the accurate tracking of TrOOP costs, was not consistently submitted to COBC in 2006. To track TrOOP costs accurately, Part D plans must have information on any prescription drug coverage that enrollees have in addition to Part D coverage. Twenty-nine percent of Part D plans did not submit their enrollees' additional drug coverage information to COBC in 2006. Most of these plans indicated that they did not have processes or systems in place to transmit this information. In addition, 36 percent of other payers that had active data-sharing agreements with COBC did not

submit their enrollees' additional drug coverage information for at least one of those agreements in 2006.

Thirty-four percent of Part D plans did not submit prescription drug event data in accordance with CMS requirements in 2006. CMS cannot verify that plans have calculated beneficiaries' TrOOP costs correctly if it does not have plans' prescription drug event (PDE) data. The PDE data include prescription drug cost and payment data that enable CMS to make payments to the plans and otherwise administer the Part D benefit. Thirty-four percent of plans, covering 49 percent of Part D beneficiaries, did not submit PDE data at the end of the first quarter or in one or more months after the first quarter of 2006. These plans were not able to meet CMS's timeframes or had technical difficulties submitting PDE files.

Sixty-three percent of Part D plans cited problems with transferring TrOOP balances when enrollees change plans. Nearly two-thirds of Part D plans reported having issues or problems with transferring TrOOP balances when enrollees change plans during the coverage year. At the time of our review, the transfer of TrOOP balances between plans relied heavily on labor- and resource-intensive processes, such as faxing transfer records or creating hundreds of compact disks with transfer information for enrollees' new plans. In addition, plans indicated that enrollees' transfer records may contain incorrect, questionable, or inconsistent data.

CMS has conducted limited oversight of Part D plans' tracking of TrOOP costs. CMS has conducted limited oversight of Part D plans' tracking of beneficiaries' TrOOP costs. The oversight CMS has conducted thus far relied on plans' self-reported data. As of April 2007, other oversight activities were either in the planning stages or in the process of being implemented.

RECOMMENDATIONS

Tracking Part D enrollees' TrOOP costs is a complex process involving coordination of many entities and data systems, as well as compliance with Part D instructions and requirements. Our findings indicate that a number of these requirements were not carried out consistently in 2006. Therefore, we recommend that CMS:

Ensure that Part D plans collect, process, and submit all data required to track enrollees' TrOOP costs in a timely manner. CMS requires that Part D plans collect and submit enrollees' additional prescription drug coverage information to COBC, process prescription drug claims and submit PDE records to CMS, and work with other Part D plans to

transfer enrollees' TrOOP balances. We recently learned that CMS is working with the National Council for Prescription Drug Programs to establish a standardized electronic system for transferring enrollees' TrOOP balance information from one plan to another in real time. CMS should continue to establish or improve automated systems to enable Part D plans to meet all data requirements related to tracking TrOOP costs.

Consider options for increasing the number of coordination of benefits agreements with other payers and ensuring that data are submitted under those agreements. Accurate tracking of TrOOP costs is dependent largely on successful coordination and sharing of prescription drug coverage information among payers and CMS contractors. CMS should ensure that all options for increasing the number of data-sharing agreements have been considered.

Because entities that provide additional drug coverage for Part D enrollees are not required by law to report such information, CMS may want to consider seeking to expand its authority to enforce agreements once they are in place. The President's 2008 Budget includes a proposal to establish a data clearinghouse that would work to determine whether private insurance or Medicare should pay for a beneficiary's health benefits. If implemented, such a clearinghouse could provide CMS with access to more comprehensive drug coverage information.

Begin or complete implementation of planned oversight activities related to the tracking of TrOOP costs. The implementation of the Part D benefit was a large undertaking for CMS, its contractors, and Part D plans. Now that the program has been in place for almost 2 years, CMS should place more emphasis on conducting oversight activities. Examining Part D plans' efforts to track TrOOP costs should be a priority given that these costs determine when beneficiaries reach each phase of the Part D benefit. OIG intends to focus future work on whether Part D plans have calculated beneficiaries' TrOOP costs correctly.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS agreed that OIG's report identified potential issues regarding the accurate tracking of TrOOP costs and that additional work is needed to ensure that Part D plans are calculating TrOOP costs correctly. CMS did not indicate whether it concurred with OIG's three

recommendations in its comments. However, CMS did note that it has taken or will take steps in response to each of OIG's recommendations, such as continuing the Part D plans' self-attestation process, enforcing compliance with data-sharing agreements, and supporting legislation to mandate insurer reporting of private insurance coverage. CMS also had questions concerning OIG's findings and suggested changes. We addressed CMS's questions and suggestions in the body of the report. We ask that CMS indicate in its final management decision whether it concurs with our recommendations.

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OBJECTIVE

1. To review the processes that Part D plans and the Coordination of Benefits Contractor (COBC) use to help ensure the accurate tracking of beneficiaries' true out-of-pocket (TrOOP) costs.
2. To determine the extent to which the Centers for Medicare & Medicaid Services (CMS) conducts oversight of Part D plans to ensure the accurate tracking of TrOOP costs.

BACKGROUND

The Medicare prescription drug program, known as Medicare Part D, provides an optional prescription drug benefit for all Medicare beneficiaries. Part D program expenditures totaled more than $47 billion in 2006.[1] As of April 2007, over 25 million Medicare beneficiaries were enrolled in Part D prescription drug plans. Part D plans are responsible for tracking beneficiaries' TrOOP costs. TrOOP costs are the prescription drug expenditures that count toward the annual out-of-pocket threshold that beneficiaries must reach before catastrophic drug coverage begins. Tracking TrOOP costs involves the coordination of many entities and data systems. The amount of beneficiaries' TrOOP costs impacts their cost sharing as well as CMS payments to Part D plans. The Office of Inspector General (OIG) conducted this initial implementation review to identify potential issues with ensuring the accurate tracking of TrOOP costs. OIG intends to focus future work on whether Part D plans have calculated beneficiaries' TrOOP costs correctly.

Medicare Prescription Drug Program

CMS contracts with companies to provide prescription drug coverage for Medicare beneficiaries. These companies sponsor plans that include stand-alone prescription drug plans (PDP) as well as Medicare Advantage-prescription drug plans (MA-PD) that offer integrated coverage for both prescription drugs and other health care. Each contract between CMS and these sponsors may include many plan

[1] "2007 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," p. 5. Available online at http://www.cms.hhs.gov/ReportsTrustFunds/downloads/tr2007.pdf. Accessed April 26, 2007.

benefit packages. Throughout this document, we refer to PDP and MA-PD contracts as Part D plans.

Standard Prescription Drug Coverage

Part D plans are required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) to offer a standard prescription drug benefit or an alternative benefit that is "actuarially equivalent" to the standard benefit. Part D plans may also offer enhanced plan benefit packages. Most beneficiaries are responsible for certain costs, which may include a monthly premium, an annual deductible, and coinsurance. However, beneficiaries with limited income are eligible to receive assistance to pay for some or all of these costs in the form of a low-income subsidy.

The standard drug benefit requires beneficiaries to pay a maximum deductible of $265 in 2007. In the initial phase of the Part D benefit, after this deductible is paid, beneficiaries contribute 25 percent coinsurance toward their drug costs and the plan pays the remaining 75 percent until combined beneficiary and plan payments reach a total of $2,400. After the $2,400 limit is reached, beneficiaries enter the coverage gap phase of the benefit in which they are responsible for 100 percent of their drug costs. The catastrophic coverage phase begins when a beneficiary's TrOOP costs reach $3,850.[2] This amount includes the beneficiary's deductible and coinsurance payments. Once beneficiaries reach $3,850 in TrOOP costs, they contribute approximately 5 percent coinsurance toward their drug costs. Of the remaining 95 percent, the Part D plans are responsible for approximately 15 percent of drug costs and CMS pays the plans 80 percent. This 80-percent reimbursement to the plans is called a reinsurance subsidy.

Calculating TrOOP Costs

Some Medicare beneficiaries with Part D coverage have additional prescription drug coverage through other entities, such as State Pharmaceutical Assistance Programs, group health plans, Medicaid programs, the Federal Employee Health Benefits Program, or

[2] In 2006, the deductible was $250 and the TrOOP costs threshold was $3,600. Available online at http://www.rds.cms.hhs.gov/downloads/Final2007PartDParameterUpdate.pdf. Accessed May 4, 2007.

TRICARE. However, only certain drug payments are eligible to be counted toward the TrOOP costs threshold.

Drug payments that count toward TrOOP costs include:

- payments made by a beneficiary or another person on behalf of a beneficiary, such as a family member;
- low-income cost sharing subsidies;
- payments by a qualified charity; and
- payments made by a State Pharmaceutical Assistance Program.

Drug payments that do not count toward TrOOP costs include:

- premiums paid by the beneficiary;
- payments made by a group health plan (e.g., employer or retiree plan);
- payments made by Government programs (e.g., Veterans Affairs or TRICARE);
- payments covered by an automobile insurer; and
- payments made by Part D plans as part of an enhanced plan benefit package.

Coordination of Prescription Drug Benefits

Part D plans are required by law to coordinate benefits with other entities that provide prescription drug coverage (42 U.S.C. § 1395w-133 and 134). Coordination of benefits enables each payer to determine its payment responsibility.[3] Coordination of benefits plays a pivotal role in the context of calculating beneficiaries' TrOOP costs because, as discussed above, prescription drug payments by some payers count toward TrOOP costs while others do not.

CMS amended the existing contract with COBC in February 2005 to include collecting information on Part D beneficiaries' additional drug coverage. COBC collects this information from other payers through Voluntary Data-Sharing Agreements, Coordination of Benefits

[3] CMS outlined coordination of benefits requirements, including requirements related to tracking TrOOP costs, in its "Part D Coordination of Benefits Guidance" issued in July 2005. This document served as the basis for the "Medicare Prescription Drug Benefit Manual" chapter on coordination of benefits issued in December 2006. Available online at http://www.cms.hhs.gov/PrescriptionDrugCovContra/dowloads/PDMChapt14COB.pdf. Accessed December 16, 2006.

Agreements, and other processes and submits the information to CMS's Medicare Beneficiary Database (MBD). Beneficiaries' additional drug coverage information is sent from the MBD to the Medicare Advantage-Prescription Drug system, which then shares a coordination of benefits data file with all Part D plans.

The MMA specifies that Part D plans have the authority to require Medicare beneficiaries to report information about additional prescription drug coverage they have (42 U.S.C. § 1395w-102(b)(4)(D)(ii)). Plans must survey their enrollees regarding additional coverage and submit this information to COBC. Part D plans transmit files containing enrollees' additional prescription drug coverage data to COBC through the Electronic Correspondence Referral System (ECRS). COBC validates the additional drug coverage data and submits it to the MBD.

CMS contracted with a TrOOP Facilitator to assist Part D plans in coordinating beneficiaries' prescription drug benefits at the point of sale. The TrOOP Facilitator is responsible for tasks such as receiving and maintaining Part D beneficiaries' eligibility information, responding to eligibility queries from pharmacies, identifying payments for prescription drugs made by other payers, and forwarding this information to Part D plans.

Prescription Drug Event Data and Reconciliation

For every prescription filled, the Part D plan must submit an electronic summary record, called the prescription drug event (PDE) record, to CMS. The PDE record contains prescription drug cost and payment data that enable CMS to make payments to the plans and otherwise administer the Part D benefit. The Part D plans were required to submit their first batch of PDE records to CMS by March 31, 2006. Thereafter, plans were required to submit PDE records to CMS at least once a month.[4] Plans must submit all PDE data, including retroactive changes, 5 months after the end of the coverage year.

The PDE information will be used in the reconciliation process, which will compare prospective payments made to Part D plans during the coverage year to actual costs as represented by the PDE data. Accurate TrOOP costs are essential to the calculation of actual costs and any

[4] CMS issued instructions to Part D plans regarding the PDE data in January 2006. The instructions were updated in April 2006.

necessary adjustments to payments to Part D plans. Part D plans cannot appeal reconciliation results based on failure to submit data in a timely manner.[5]

METHODOLOGY

Part D Plan Sample

When we selected the sample in August 2006, CMS had 91 PDP contracts and 474 MA-PD contracts with Part D sponsors. We excluded from the sampling frame 12 PDP plans because they were direct contracts between CMS and employers or contracts with insurers that offer plans on behalf of employers. We excluded 77 MA-PD plans because they were cost plans, Program of All-Inclusive Care for the Elderly plans, or demonstration plans.[6] We also excluded 1 PDP and 18 MA-PDs that had fewer than 20 enrollees each as of June 7, 2006.

As shown in the table below, we divided the remaining 457 plans into four strata based on the type of plan and number of enrollees in each plan. The plans in stratum 2 and stratum 4 represent the top five PDP and MA-PD plans, respectively, by enrollment. We selected a stratified simple random sample of 142 Part D plans. The sample was designed to produce statistical estimates with an expected precision of +/-10 percent at the 95-percent confidence level. After selecting the sample, we learned that one MA-PD was an employer-based contract that should have been excluded from the sampling frame. We removed this contract from the sample, for a total sample of 141 Part D plans.

Table - Sample of Part D Plans

Stratum Definition	Number of Part D Plans in Sampling Frame	Number of Part D Plans in Final Sample
1. PDPs with fewer than 537,486 enrollees	73	45
2. PDPs with 852,712 to 3.3 million enrollees	5	5
3. MA-PDs with fewer than 121,056 enrollees	374	86
4. MA-PDs with 179,805 to 637,664 enrollees	5	5
Total	**457**	**141**

[5] "CMS 2005 Prescription Drug Event Training Participant Guide," p.12-2. Accessed online May 6, 2006. This version of the guide is no longer available online.

[6] These types of plans were excluded from the sampling frame because they may have had Part D requirements that differed from those of PDP and MA-PD plans.

Data Collection

To identify the processes that Part D plans use to ensure the accurate tracking of TrOOP costs, we conducted an online survey and collected documentation from our sample of Part D plans between January and March 2007. We requested that the plans provide documentation outlining their policies and/or processes for tracking TrOOP costs. We received survey responses for 138 Part D plans. Three Part D plans did not respond to our survey after multiple e-mail and telephone follow-up efforts to obtain their responses. We received responses from 48 of 50 PDPs and 90 of 91 MA-PDs. These plans covered 79 percent of Medicare beneficiaries enrolled in Part D plans as of June 2006.

We conducted an onsite interview with CMS staff in October 2006 to determine what oversight processes CMS has in place to ensure the accurate tracking of TrOOP costs and to learn the results of these processes. The interview focused on CMS's oversight of the Part D plans. We also collected relevant documentation from CMS, such as policies and analysis spreadsheets.

To determine the processes that COBC uses to help ensure the accurate tracking of TrOOP costs, we conducted an onsite interview with COBC staff in October 2006 and obtained relevant documentation. To gain a better understanding of the functions of the TrOOP Facilitator, we conducted an onsite interview with a representative of the TrOOP Facilitator in October 2006 and obtained related documents.

Data Analysis

We aggregated quantitative Part D plan survey results to analyze plans' procedures related to tracking enrollees' TrOOP costs, including communicating with enrollees to obtain additional drug coverage information, processing changes to enrollees' TrOOP balances, transferring TrOOP balances when enrollees change plans, and submitting required data to COBC and CMS. Based on plan survey results, we calculated weighted estimates of the percentage of enrollees affected by particular plan characteristics. All statistical estimates reflect the stratified simple random sample design and are provided in Appendix A.

We reviewed and analyzed quantitative data files provided to OIG by CMS and COBC in connection with our interviews. We analyzed narrative responses to open-ended questions that Part D plans recorded in the online survey. Finally, we analyzed narrative responses that

CMS, COBC, and TrOOP Facilitator staff provided during onsite interviews.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

Information on enrollees' additional drug coverage, essential for the accurate tracking of TrOOP costs, was not consistently submitted to COBC in 2006

To track TrOOP costs accurately, Part D plans must have information on any prescription drug coverage that enrollees have in addition to Part D coverage. The COBC has processes in place to collect information on Medicare beneficiaries' additional drug coverage. One process requires that Part D plans submit enrollee survey data and another involves the establishment and implementation of data-sharing agreements with other payers of prescription drug benefits.

Twenty-nine percent of Part D plans did not submit enrollees' additional drug coverage data to the Coordination of Benefits Contractor in 2006

CMS requires Part D plans to survey their enrollees within 30 days of enrollment and annually thereafter and submit to COBC information regarding any prescription drug coverage enrollees have in addition to Part D coverage. Our January 2007 survey of Part D plans indicates that 93 percent of plans had conducted an initial enrollee survey. However, 29 percent of plans reported that they did not submit their enrollees' additional drug coverage information to COBC in 2006. These plans covered 25 percent of Part D enrollees. Most of these plans indicated that they had neither a manual process nor an electronic system for submitting the required information or they had problems connecting to the ECRS.

Part D plans need information concerning enrollees' additional prescription drug coverage to track TrOOP costs accurately. For example, an enrollee may have additional prescription drug coverage through a group health plan that makes drug payments on the enrollee's behalf that do not count towards TrOOP costs. If an enrollee's Part D plan is not aware of this additional drug coverage, the enrollee's TrOOP costs will accumulate more quickly because payments made by the other plan would not be removed from the enrollee's TrOOP balance. As a result, the enrollee may not be in the correct phase of the Part D benefit.

Part D plans' records containing enrollees' additional drug coverage information were often rejected by the ECRS. COBC provided data to OIG indicating that, as of October 2006, many of the records plans submitted containing enrollees' additional drug coverage data had been rejected by the ECRS. In some cases, over 85 percent of a plan's records submitted to the ECRS were rejected. COBC explained that records

submitted to the ECRS were rejected because plans submitted incorrect data. For example, a plan may have sent an internal enrollee policy number instead of the Health Insurance Claim Number that the ECRS requires to identify a Medicare beneficiary. As a result, information on beneficiaries' additional drug coverage cannot be incorporated into the MBD. In October 2006, COBC indicated that it had conducted a number of training sessions for Part D plans on submitting enrollees' additional drug coverage data to the ECRS. However, COBC also reported that plans were just beginning to focus on submitting these data, having spent the earlier part of 2006 focusing on other aspects of implementing the Part D benefit.

Thirty-six percent of entities that had data-sharing agreements with the Coordination of Benefits Contractor did not submit their enrollees' additional drug coverage information for at least one of those agreements

To facilitate the exchange of coverage information, COBC establishes data-sharing agreements with other payers. These voluntary agreements are called Coordination of Benefits Agreements (COBA) and Voluntary Data-Sharing Agreements (VDSA). Entities may have more than one COBA with COBC. According to data provided by COBC, 36 percent (57 of 160) of entities that had active data-sharing agreements did not provide enrollees' additional drug coverage information to COBC for at least one of those agreements in 2006. In particular, 55 percent (42 of 76) of entities with active COBAs did not provide enrollees' additional drug coverage information to COBC for at least one of those agreements in 2006. Eighteen percent (15 of 84) of entities with VDSAs had not provided enrollees' additional drug coverage information to COBC as of October 2006. As stated above, information on enrollees' additional prescription drug coverage is essential for successful coordination of benefits and accurate tracking of TrOOP costs.

There are time- and money-saving incentives for non-Medicare payers to establish data-sharing agreements and provide drug coverage data to COBC.[7] However, other payers of drug benefits are not required to provide coverage information to COBC. As a result, even though payers have established data-sharing agreements to provide additional drug

[7] One incentive is that employers with VDSAs can obtain Medicare entitlement data monthly or quarterly rather than spending up to 2 years to obtain such information through other methods.

coverage data, COBC can only encourage these payers to fulfill their obligations under those agreements. COBC also indicated that the data-sharing process requires a great deal of technological and other resources. For example, establishing a telecommunication line for electronic transmission of data alone can take up to 60 days and cost $5,000 a month to maintain. In addition, setting up the data-sharing files and testing the process can take a considerable amount of time. Therefore, data-sharing agreements may be in place for some time before the data-sharing process is successfully implemented.

Thirty-four percent of Part D plans did not submit prescription drug event data in accordance with CMS requirements in 2006

According to CMS's "Updated Instructions: Requirements for Submitting Prescription Drug Event Data," Part D plans were required to submit PDE data at the end of the first quarter of 2006 and at least once per month thereafter. Without plans' PDE data, CMS cannot verify that plans have calculated beneficiaries' TrOOP costs correctly. Thirty-four percent of plans did not submit PDE data at the end of the first quarter or in one or more months after the first quarter of 2006. These plans covered 49 percent of Medicare beneficiaries enrolled in Part D plans. The plans indicated that they submitted PDE data outside CMS's required timeframes, had technical difficulties submitting PDE data files, or had problems or delays obtaining Part D prescription drug data from their pharmacy benefit managers. Of the plans that did not submit PDE data in accordance with CMS requirements, three-quarters failed to submit data in one or more months after the first quarter of 2006.

CMS provided OIG with information indicating that CMS had taken steps to follow up with Part D plans that were not complying with PDE data certification and submission requirements in 2006. CMS sent warning letters in June 2006 to Part D plans that had not submitted test PDE data files and were not yet certified to submit PDE data to CMS. CMS issued corrective action plans in August 2006 to Part D plans that remained noncompliant with CMS's PDE data testing and certification requirements.

Sixty-three percent of Part D plans cited problems with transferring TrOOP balances when enrollees change plans

When a beneficiary changes from one Part D plan to another, CMS requires the disenrolling plan to transmit a Transfer Explanation of Benefits (EOB) to the beneficiary's new plan of record within 7 days of disenrollment. This record must contain the beneficiary's TrOOP balance and the total payments the plan has made to pharmacies on the beneficiary's behalf. If this information is not received by the new plan or is not accurate, the beneficiary may not be in the correct phase of the benefit (i.e., initial coverage, coverage gap, or catastrophic coverage). Overall, 63 percent of Part D plans, covering 78 percent of Part D enrollees, reported having issues or problems with transferring TrOOP balances when enrollees change plans during the coverage year. These problems included manual processes for transferring TrOOP balance records and the receipt of incorrect, questionable, or inconsistent TrOOP balance data.

Two-fifths of Part D plans had issues or problems with the resource-intensive nature of the TrOOP balance transfer process

Forty percent of plans indicated that the labor- and resource-intensive nature of the process was an issue or a problem. Plans indicated that the transfer of TrOOP balances relied heavily on manual processes, such as faxing paper copies of Transfer EOB records to the new Part D plan or creating hundreds of compact disks containing enrollee TrOOP balance information for new plans. According to the "Medicare Prescription Drug Benefit Manual," CMS is considering options for automating this process in the future.

About one-quarter of Part D plans reported that Transfer Explanation of Benefits records contained incorrect or questionable information

Twenty-eight percent of plans indicated that they received Transfer EOB records containing incorrect or questionable TrOOP balances. For example, the EOB record might contain the amount of the most recent change in the enrollee's TrOOP balance rather than the total TrOOP balance. Nine plans reported receiving EOB records with TrOOP balances that were greater than the total payments made to pharmacies, calling into question the validity of the information.

One-quarter of plans indicated that the information in the effective date field on the Transfer EOB record was incorrect. According to the "Medicare Prescription Drug Benefit Manual," the effective date on the

Transfer EOB record should be the date that the reported TrOOP balance and total payments made to pharmacies were calculated. However, plans indicated that this field might include the date that the EOB record was created or the enrollee's eligibility effective date. Without correct information concerning the date an enrollee's TrOOP balance was last calculated by a previous plan, the new Part D plan cannot determine what subsequent TrOOP cost accumulations should be applied to the enrollee's current TrOOP balance.

Multiple Transfer Explanation of Benefits records per enrollee made accurate calculation of TrOOP costs difficult for some Part D plans

After a beneficiary changes Part D plans and the Transfer EOB is sent to the new plan, it is still possible that the beneficiary's previous plan may revise his or her TrOOP balances based on new or updated information it receives from pharmacies or other payers. In such cases, CMS requires the previous plan to provide the new plan with an updated EOB record reflecting the new TrOOP balance. Twelve of the plans that cited issues or problems with the TrOOP balance transfer process indicated that they had received multiple EOB records for one enrollee. Plans indicated that they received EOB records that were exact duplicates or had duplicate information but different TrOOP balances. Some plans received multiple EOBs for enrollees who had more than one plan benefit package during the coverage year. In all of these circumstances, plans indicated that it was difficult to determine which reported TrOOP cost amount to apply to the enrollee's new TrOOP balance.

CMS has conducted limited oversight of Part D plans' tracking of TrOOP costs

CMS has conducted limited oversight of Part D plans' tracking of beneficiaries' TrOOP costs. The oversight CMS has conducted thus far relied on plans' self-reported data. These data indicated that most plans were not in full compliance with coordination of benefits and TrOOP tracking requirements in at least the first half of 2006.

CMS's oversight of plans' compliance with requirements related to tracking TrOOP costs relied on self-reported data from Part D plans in 2006

As described previously, CMS asked Part D plans to attest to their compliance with all of the requirements outlined in CMS's 2006 Coordination of Benefits Guidance. CMS provided OIG with the results of this effort. Based on plans' attestations, 405 of 501 plans (81 percent) were not in compliance with one or more of all requirements. A total of

261 of these plans were not in compliance with one or more of four requirements specifically related to calculating TrOOP costs. These requirements included tracking TrOOP costs in real time, adjusting TrOOP balances based on claims received in other than real time, and transferring a beneficiary's TrOOP balance to another Part D plan when the beneficiary disenrolls during the coverage year. Plans that scored below a certain number of points based on their attestations were required to complete a business plan for achieving compliance with all coordination of benefits requirements, including those related to tracking TrOOP costs. According to CMS, 21 percent of plans (106 of 501) were required to submit either business plans specifying actions they would take to become compliant or attestations indicating that actions had already been taken to achieve compliance with all requirements.

As of April 2007, other CMS oversight activities regarding Part D plans' tracking of TrOOP costs were either in the planning stages or in the process of being implemented

CMS finalized protocols for conducting routine audits of Part D plans' processes and procedures in April 2006. These guides include elements related to the coordination of benefits and TrOOP costs, such as ensuring that plans have systems in place to collect information on enrollees' additional drug coverage and to track expenditures made by other payers to determine if enrollees have reached the TrOOP threshold. As of April 2007, no audits had been conducted. Our survey of Part D plans confirmed that CMS has not conducted any individual performance reviews regarding plans' tracking of TrOOP costs.

Part D regulations require that CMS conduct financial audits of at least one-third of Part D plans each year (42 CFR § 423.504(d)). According to CMS staff, these financial audits will include elements related to plans' tracking of TrOOP costs. However, CMS had not finalized the financial audit program and audit guide. CMS had not yet obtained contractors to conduct the financial audits. According to CMS staff, financial audits for contract year 2006 are not scheduled to begin before January 2008.

CMS staff indicated in October 2006 that its contractor was analyzing a sample of PDE data that Part D plans submitted to CMS. The purpose of the analysis was to determine whether Part D plan PDE data confirmed that plans administered the Part D benefit in a manner consistent with both CMS requirements and plan benefit packages'

structures. As of April 2007, CMS indicated that no formal findings from the PDE data analysis have been issued.

To calculate TrOOP costs correctly, information on enrollees' additional prescription drug coverage must be submitted by Part D plans as well as by entities that have data-sharing agreements with COBC. Plans must also transfer accurate enrollee TrOOP balance information to and from other plans when enrollees change plans during the coverage year. In addition, CMS must have Part D plans' PDE data to verify that plans have calculated TrOOP costs correctly. Our findings indicate that these requirements were not carried out consistently in 2006. CMS is responsible for the oversight of Part D plans' tracking of TrOOP costs. Therefore, we recommend that CMS:

Ensure That Part D Plans Collect, Process, and Submit All Data Required To Track Enrollees' Troop Costs in a Timely Manner

As described in this report, CMS requires that Part D plans collect and submit enrollees' additional prescription drug coverage information to COBC, process prescription drug claims and submit PDE records to CMS, and work with other Part D plans to transfer enrollees' TrOOP balances. We recently learned that CMS is working with the National Council for Prescription Drug Programs (NCPDP) to establish a standardized electronic system for transferring enrollees' TrOOP balance information from one plan to another in real time.[8] CMS should continue to establish or improve automated systems to enable Part D plans to meet all data requirements related to tracking TrOOP costs.

Consider Options for Increasing the Number of Coordination of Benefits Agreements With Other Payers and Ensuring That Data Are Submitted Under Those Agreements

Accurate tracking of TrOOP costs is dependent largely on successful coordination and sharing of prescription drug coverage information among payers and CMS contractors. CMS should ensure that all options for increasing the number of data-sharing agreements have been considered.

Because entities that provide additional drug coverage for Part D enrollees are not required by law to report such information, CMS may want to consider seeking to expand its authority to enforce agreements

[8] NCPDP is a not-for-profit Standards Development Organization consisting of over 1,450 members from the pharmacy services industry.

once they are in place. The President's 2008 Budget includes a proposal to establish a data clearinghouse that would work to determine whether private insurance or Medicare should pay for a beneficiary's health benefits. If implemented, such a clearinghouse could provide CMS with access to more comprehensive drug coverage information.

Begin or Complete Implementation of Planned Oversight Activities Related to the Tracking of Troop Costs

The implementation of the Part D benefit was a large undertaking for CMS, its contractors, and Part D plans. Now that the program has been in place for almost 2 years, CMS should place more emphasis on conducting oversight activities. Examining Part D plans' efforts to track TrOOP costs should be a priority given that these costs determine when beneficiaries reach each phase of the Part D benefit. OIG intends to focus future work on whether Part D plans have calculated beneficiaries' TrOOP costs correctly.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS agreed that OIG's report identified potential issues regarding the accurate tracking of TrOOP costs and that additional work is needed to ensure that Part D plans are calculating TrOOP costs correctly. CMS did not indicate whether it concurred with OIG's three recommendations in its response. However, CMS did note that it has taken or will take steps in response to these recommendations. For the full text of CMS's comments, see Appendix B.

In response to the recommendations, CMS stated that it intends to continue the process of asking Part D plans to self-attest to their compliance or noncompliance with coordination of benefits requirements, including those specific to TrOOP, and intends to follow up with plans that report noncompliance. CMS is revising the 2008 Part D Explanation of Benefits letter to include TrOOP balances reported by prior plans to an enrollee's current plan. In addition, CMS intends to use PDE data to monitor TrOOP accumulation after reconciliation activities for 2006 have been completed. CMS reported that it is beginning to enforce the full terms of its data-sharing agreements by notifying data-sharing partners that their access to Medicare entitlement data will be suspended if they do not comply with their agreements. CMS also stated that it continues to support legislative proposals for mandatory insurer reporting of private insurance coverage. CMS stated again that it plans to conduct financial

audits of one-third of Part D plans for contract year 2006. According to CMS, one aspect of these audits will be to examine, in general, how Part D plans track TrOOP costs.

CMS provided comments on two OIG findings. CMS suggested that OIG had incorrectly stated that inaccurate tracking of TrOOP costs could lead an enrollee to reach the coverage gap sooner. CMS also stated that the number of entities with data-sharing agreements that did not submit enrollees' other prescription drug coverage information to COBC included entities such as Medicaid agencies that did not provide drug coverage and, therefore, did not have drug coverage information to submit. CMS calculated different figures and suggested that OIG incorporate them in its report.

We addressed the comments CMS provided about our findings. We clarified that an enrollee may not be in the correct phase of the Part D benefit if his or her TrOOP costs are not calculated accurately. We requested the source data from COBC that CMS used to develop the figures in its comments regarding entities with data-sharing agreements that did not provide required drug coverage information to COBC in 2006. After receiving revised data from CMS, we updated the figures in our report regarding entities with active COBAs or VDSAs that did not provide drug coverage information to COBC in 2006 as required. The figures in our final report differ from those in CMS's comments because the electronic data underlying CMS's comments covered a different time period than our report and was not reconciled against hard-copy data-sharing agreements. In addition, as a technical clarification, the COBC confirmed in follow-up discussions that several Medicaid agencies had data-sharing agreements in place for which they submitted drug coverage information in 2006.

We ask that CMS indicate in its final management decision whether it concurs with our recommendations.

APPENDIX ~ A

The table below contains estimates presented in the Findings section of this report. Point estimates and confidence intervals were weighted based on the stratified simple random sample design and are reported at the 95-percent confidence level.

Estimates and Confidence Intervals		
Part D Plan Characteristic	**Point Estimate**	**95-Percent Confidence Interval**
Part D plans that conducted an initial survey of enrollees	93.3%	89.6% - 97.1%
Part D plans that did not submit enrollees' additional drug coverage information to COBC in 2006	29.4%	22.3% - 36.4%
Part D enrollees covered by plans that did not submit enrollees' additional drug coverage information to COBC in 2006	25.4%	18.8% - 32.0%
Part D plans that did not submit PDE data in accordance with CMS requirements in 2006	33.8%	26.3% - 41.2%
Part D enrollees covered by plans that did not submit PDE data in accordance with CMS requirements in 2006	49.2%	42.8% - 55.6%
Part D plans that cited problems with transferring TrOOP balances to or from other plans	63.2%	55.6% - 70.7%
Part D enrollees covered by plans that cited problems with transferring TrOOP balances to or from other plans	78.4%	73.6% - 83.2%
Part D plans that cited the labor- and resource-intensive nature of the TrOOP balance transfer process as an issue or problem	39.9%	32.1% - 47.7%
Part D plans that received Transfer EOB records with incorrect or questionable TrOOP balances	28.4%	21.1% - 35.7%
Part D plans that received Transfer EOB records with incorrect effective dates	25.0%	18.0% - 32.0%

APPENDIX ~ B

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: SEP 18 2007

TO: Daniel R. Levinson
Inspector General

FROM: Kerry Weems
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Tracking Beneficiaries' True Out-of-Pocket Costs for the Part D Prescription Drug Benefit" (OEI-03-06-00360)

Thank you for the opportunity to review and comment on the OIG draft report to evaluate the processes Part D plans and the Coordination of Benefits Contractor (COBC) use to help ensure the accurate tracking of beneficiaries' true out-of-pocket (TrOOP) costs and the extent to which the Centers for Medicare & Medicaid Services (CMS) conducts oversight of Part D plans to ensure the accurate tracking of TrOOP costs.

We agree that this initial review by the OIG identifies potential issues with ensuring the accurate tracking of TrOOP costs and that further work is needed to ensure that the plans are correctly calculating these costs.

OIG Finding

The OIG found that information on enrollees' additional drug coverage, essential for the accurate tracking of TrOOP costs, was not consistently submitted to COBC in 2006.

CMS Response

Part D Plan Reporting

The report states both that "Twenty-nine percent of Part D plans did not submit enrollees' additional drug coverage data to the Coordination of Benefits Contractor in 2006" and that 302 of 501 Part D plans (60 percent) reported they were not in compliance with the requirement to submit their enrollees' additional drug coverage information to COBC. It is somewhat confusing to provide these two vastly different figures without trying to interpret the difference between them. To that end, we believe it should be noted that the data were collected at different points in time; i.e., the latter results were based on plan responses to the CMS Coordination of Benefits attestation in June 2006 and the former on plan responses to the OIG's January 2007 survey, suggesting considerable improvement may have occurred during the second half of 2006.

Within the discussion of this finding, the report also states that if a plan does not take secondary coverage into account and track TrOOP accurately, the enrollee will reach the coverage gap sooner. This is incorrect. The beneficiary's movement through the benefit is based on his/her gross covered drug costs; TrOOP is used to determine when catastrophic coverage begins.

Reporting from Other Payers

The statement supporting this finding that "...76 percent of other payers that had active data sharing agreements with COBC did not submit their enrollees' additional drug coverage information for at least one of those agreements in 2006" is incorrectly calculated. Many of the Coordination of Benefits Agreements (COBA) trading partners included in the base number of agreements do not offer a prescription drug benefit and would never have supplemental drug records to report to CMS.

Of the 369 entities with COBAs, only about 70 would have supplemental drug coverage to report to CMS. For example, one group of COBA partners includes State Medicaid agencies. They would never have supplemental drug coverage to report to Medicare under their COBA. Therefore, instead of saying that "92 percent (340 of 369) of entities with active COBAs did not provide enrollees' additional drug coverage information...," it should state that "59 percent (41 of 70) of entities with active COBAs, and which would have supplemental coverage to report, did not provide enrollees' additional drug coverage information..." The same statement can be said of the Voluntary Data Sharing Agreements (VDSA) reporting statistics in this draft report. CMS is in the process of collecting updated statistics regarding VDSA and COBA supplemental drug reporting.

OIG Finding

The OIG found that thirty-four percent of Part D plans did not submit prescription drug event data in accordance with CMS requirements in 2006.

CMS Response

We note that the inability of Part D plans to submit prescription drug event (PDE) data by March 2006 and at least once a month thereafter would not necessarily imply that the plans are unable to accurately track beneficiaries' TrOOP costs. The primary purpose of the PDE data is to help facilitate reconciliation. To the extent that PDE data will be used to determine whether plans accurately calculated TrOOP costs, such analysis would not occur prior to reconciliation. Further, plans' failure to submit the data monthly would not necessarily effect payment reconciliation as long as the PDE data were received by the final end-of-year deadline specified by CMS. This latter date was extended to July 30, 2007 for the 2006 PDEs.

OIG Recommendation

The OIG recommends CMS ensure that Part D plans collect, process, and submit all data required to track enrollees' TrOOP costs in a timely manner.

CMS Response

The CMS will follow up the 2006 coordination of benefits (COB) attestation process by contacting the 261 plans that previously indicated non-compliance with one or more of the four requirements specifically related to plan tracking of TrOOP costs to determine the current status of their TrOOP-related processes. Follow-up will also be made with those 106 plans from which a business plan was previously requested; we require that those plans that remain non-compliant develop and complete corrective action plans that entail the involvement of a contractor to assist in the plan's correction activities.

On an on-going basis, CMS will require that all new plan sponsors complete a COB attestation in their first contract year. Plans that are not fully compliant will be required to identify the requirements with which they do not comply and explain their rationale for not meeting these requirements. In addition, to monitor the compliance of existing plans, a sample of one-third of the plan sponsors with existing Part D contracts will be required to re-attest to their compliance with the COB requirements. Those unable to attest to full compliance will be required to develop and complete a business plan.

Although to date CMS has received few complaints concerning plans' tracking of TrOOP costs, we will continue to examine the complaints received to identify any patterns concerning specific plan sponsors. If we identify such patterns, we will follow our standard operating procedures for investigating potential compliance issues and will take appropriate corrective action as required. In addition, for 2008, we are revising our model Part D Explanation of Benefits letter to provide beneficiaries additional information, including specifying in a new separate variable field the TrOOP-related amounts reported by prior plans to the current plan of record which have been subsequently incorporated into the beneficiaries' TrOOP costs. This additional information will enable beneficiaries to identify problems that previously may have gone undetected and to register complaints when warranted.

CMS has developed reports in our Drug Data Processing System (DDPS) to accumulate TrOOP-eligible amounts reported on prescription Drug Event (PDE) data in order to monitor TrOOP accumulation and whether beneficiary claims are appropriately adjudicated above the annual out-of-pocket threshold. Once reconciliation activities have been completed, we will be reviewing these reports and taking appropriate follow-up action at that time. We are also planning additional future analyses of benefit adjudication based on PDE data.

OIG Recommendation

The OIG recommends CMS consider options for increasing the number of coordination of benefits agreements with other payers and ensuring that data are submitted under those agreements.

CMS Response

Beyond the primary reason insurers sign COBAs, which is to have Medicare electronically cross Medicare primary claims over to providers for secondary payment, insurers are now given the opportunity to build query transactions to Medicare under the provision that they provide us with supplemental drug coverage reporting data in exchange for Medicare entitlement data. Trading partners are obligated under the terms of their COBA to report supplemental drug coverage data to CMS or risk losing access to the ability to query for Medicare entitlement data. As mentioned in the audit, many data partners were applying more of their resources to getting their own Part D programs up and running and spending fewer resources on coordination of benefits issues, and CMS was accepting of that when deciding whether to strictly enforce the terms of the data sharing agreements. Now that the Part D program has been in operation for two years and the initial start-up operations are up and running, CMS is beginning to enforce the full terms of its various data sharing agreements. CMS has sent notices to data partners informing them that if they do not begin meeting the full terms of their COBAs or VDSA, CMS will begin suspending their access to Medicare entitlement data. These initial notices have resulted in many of our partners coming into compliance with the terms of their data sharing agreements with CMS.

The OIG also suggested that CMS may want to consider seeking to expand its authority to enforce agreements once they are in place. CMS has consistently and repeatedly supported mandatory insurer reporting of private insurance coverage though various legislative proposals. In the absence of any legal requirements to report such data, access to Medicare data though VDSAs or COBAs is the single biggest incentive for insurers and employers to provide CMS with private prescription drug coverage data and, now that Part D is operational, the CMS is enforcing full compliance of the terms of its COBC administered VDSAs and COBAs.

OIG Recommendation

The OIG recommends CMS begin or complete implementation of planned oversight activities related to the tracking of TrOOP costs.

CMS Response

One aspect of the financial audits of 1/3 of the Part D plans will be to look at how, in general, Part D plans are tracking TrOOP costs. CMS is using contractor support for this review and expects to make awards to contractors in early fall 2007. Options to address overall Part D plan compliance are currently being discussed.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Linda M. Ragone, Deputy Regional Inspector General.

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