Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE DRUG PLAN SPONSORS' IDENTIFICATION OF POTENTIAL FRAUD AND ABUSE

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EXECUTIVE SUMMARY

OBJECTIVES

To determine:

1. the extent to which Medicare stand-alone prescription drug plan sponsors identified potential fraud and abuse;
2. the type of potential fraud and abuse that these plan sponsors identified; and
3. the extent to which these plan sponsors conducted inquiries, initiated corrective actions, and made referrals for further investigation regarding potential fraud and abuse.

BACKGROUND

As of January 1, 2006, Medicare beneficiaries could obtain prescription drug coverage under the Medicare Part D program. Part D expenditures for 2007 were approximately $49.5 billion. As of August 2008, 26 million beneficiaries were enrolled in Part D and two-thirds were in stand-alone drug plans.

Plan sponsors are private companies that contract with the Centers for Medicare & Medicaid Services (CMS) to provide Part D drug coverage to Medicare beneficiaries. Sponsors are required to have a comprehensive program to detect and deter fraud and abuse. They can identify potential fraud and abuse through internal efforts such as claim reviews, and through complaints or referrals from external sources such as CMS, Medicare Drug Integrity Contractors (MEDIC), law enforcement agencies, beneficiaries, and pharmacy providers.

Upon identifying potential fraud and abuse, sponsors are required to conduct an inquiry and initiate appropriate corrective action. CMS recommends that sponsors refer potential fraud and abuse incidents to MEDICs and/or law enforcement agencies.

The only type of fraud and abuse information CMS requires sponsors to report to CMS is the aggregate number of fraud and abuse complaints they received directly from beneficiaries each quarter.

We analyzed data representing the first 6 months of 2007 from 86 of 91 stand-alone drug plan sponsors. We did not include 5 of the 91 plan sponsors because 1 had been terminated from the program, 1 was under investigation, and the other 3 did not provide data in time to be included in our review.

FINDINGS

Overall, 24 of 86 Part D stand-alone plan sponsors did not identify any potential fraud and abuse incidents; most potential fraud and abuse incidents were associated with only a small number of plan sponsors. Twenty-four plan sponsors (28 percent) did not identify any potential fraud and abuse incidents in the first 6 months of 2007 either from internal efforts or complaints from external sources. Of the 62 plan sponsors that identified a total of 9,774 incidents of potential fraud and abuse during this period, 7 plan sponsors accounted for 90 percent of all incidents. One of the seven plan sponsors identified 67 percent of all incidents.

Plan sponsors identified 78 percent of all potential fraud and abuse incidents through internal efforts; however, 42 plan sponsors did not identify any potential fraud and abuse through internal efforts. One plan sponsor was associated with 84 percent of the potential fraud and abuse identified through internal efforts.

Twenty-two percent of potential fraud and abuse incidents identified came from external sources; however, 34 plan sponsors did not identify any potential fraud and abuse incidents from external sources. Two plan sponsors had the majority (51 percent) of these incidents.

Inappropriate billing was the most prevalent type of potential fraud and abuse incident identified, and pharmacies were associated with most of the potential fraud and abuse incidents. Plan sponsors identified 26 different types of fraud and abuse (both from internal efforts and complaints from external sources). Of the 26 types, the most prevalent type was inappropriate billing, which accounted for 9,073 incidents. An example of inappropriate billing is submitting claims for drugs not provided.

Plan sponsors identified 11 types of persons or entities associated with potential fraud and abuse. Pharmacies/pharmacists were most often associated with these incidents.

Not all 62 plan sponsors that identified potential fraud and abuse incidents conducted inquiries, initiated corrective actions, or made referrals for further investigation. Three actions that plan sponsors can take after identifying potential fraud and abuse are conducting inquiries, initiating corrective actions, and referring incidents for further investigation. Of the 62 plan sponsors that identified incidents of potential fraud and abuse, 47 conducted inquiries, 32 initiated

corrective actions, and 33 referred incidents to other entities for further investigation. Overall, 17 plan sponsors initiated all three actions, 21 initiated two actions, 19 initiated one action, and 5 did not initiate any of these actions.

RECOMMENDATIONS

Plan sponsors are the first line of defense against Part D fraud and abuse. However, we found that some plan sponsors did not identify any potential fraud and abuse incidents. Moreover, some of the plan sponsors that identified potential fraud and abuse incidents did not initiate inquiries, corrective actions, or referrals.

CMS does not routinely collect information that would describe the overall volume or types of Part D fraud and abuse that occur or that would inform CMS as to the effectiveness of the comprehensive fraud and abuse plan each sponsor is required to have in place. The only information that CMS requires plan sponsors to report to CMS concerning fraud and abuse is the quarterly aggregate number of fraud and abuse complaints that plan sponsors receive from beneficiaries.

A crucial aspect of protecting the integrity of the Part D program is ensuring that the plan sponsors have a comprehensive and effective program to detect and deter fraud and abuse. Therefore, we recommend that CMS:

Review Part D plan sponsors to determine why certain sponsors have identified especially high or low volumes of potential fraud and abuse incidents.

Determine whether the Part D plan sponsors that identified potential fraud and abuse initiated inquiries and corrective actions as required by CMS, and made referrals for further investigation as recommended by CMS.

Require Part D plan sponsors to maintain and routinely report information related to the results of sponsors' fraud and abuse programs.

Use this required information to help determine the effectiveness of sponsors' fraud and abuse programs.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS stated that it is committed to combating fraud, waste, and abuse in the Part D program but that because of limited funding, it has not been able to perform as much direct oversight of the Part D sponsors' fraud, waste, and abuse efforts as expected.

In response to OIG's first recommendation, CMS stated that it agreed that the variability in the number of potential fraud and abuse incidents identified by sponsors is a concern and that CMS will examine the data more closely by referring the findings to MEDICs. CMS also stated that it intends to revise the reporting requirements and give sponsors more specific guidance on how to track and properly label incidents, e.g., as an education issue or a potential fraud issue.

CMS concurred with OIG's second recommendation and will refer the data in this report to MEDICs for further investigation.

Although CMS provided comments about OIG's third recommendation, CMS did not state whether it concurred. CMS did state that OIG's report would be useful when CMS initiates its Part D sponsor compliance plan audits. CMS stated that our report will help ensure that sponsors are conducting their own internal investigations and taking appropriate corrective actions. CMS did not address OIG's fourth recommendation.

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INTRODUCTION

OBJECTIVES

To determine:

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2. the type of potential fraud and abuse that these plan sponsors identified; and
3. the extent to which these plan sponsors conducted inquiries, initiated corrective actions, and made referrals for further investigation regarding potential fraud and abuse.

BACKGROUND

As of January 1, 2006, Medicare beneficiaries could obtain prescription drug coverage under the Medicare Part D program (hereinafter Part D).[1] Part D expenditures for 2007 were approximately $49.5 billion.[2]

Stand-Alone Drug Plan Coverage

Stand-alone drug plan coverage refers to a plan for prescription drugs only. Beneficiaries who enroll in Part D have the option to receive their drug coverage from a stand-alone drug plan sponsor or a managed-care plan sponsor that covers other medical benefits in addition to prescription drugs.

Two-thirds of the 26 million beneficiaries enrolled in Part D as of August 2008 were enrolled in plans offered by stand-alone plan sponsors.[3]

Prescription Drug Plan Sponsors

Prescription drug plan sponsors (plan sponsors) are private companies that provide Part D drug coverage to Medicare beneficiaries. The Centers for Medicare & Medicaid Services (CMS) makes monthly prospective payments to sponsors for each of the beneficiaries covered

[1] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 101; P.L. No. 108-173 § 101; Social Security Act, § 1860D-1(a)(2); 42 U.S.C. § 1395w-101(a)(2).

[2] The Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, "2008 Annual Report," p. 111. Available online at http://www.cms.hhs.gov/ReportsTrustFunds/downloads/tr2008.pdf. Accessed on April 22, 2008.

[3] CMS, "Monthly Contract and Enrollment Summary Report." Available online at http://www.cms.hhs.gov/MCRAdvPartDEnrolData/. Accessed on September 29, 2008.

by the sponsors' plans. The payments are based on estimates that sponsors provide in their approved bids prior to the beginning of the plan year. Sponsors' bids are based on their actual costs from the base year. After the close of the plan year, CMS must reconcile the payments with the sponsors' actual costs to determine whether sponsors owe money to Medicare or Medicare owes money to sponsors based on legislatively mandated risk-sharing percentages.[4] Thus, under Part D, both Medicare and sponsors share the profits and losses of providing the benefit.

CMS contracts with plan sponsors to provide drug plans in designated regions. CMS established 39 stand-alone drug plan regions in 2007. Of the 39 regions, 25 included one State each, 9 included multiple States, and the remaining 5 included one U.S. territory each. Plan sponsors may offer plans in one or more regions and may offer plans with different features within each region. Plan sponsors may also offer plans to employer/union groups.

Plan sponsors may use related entities and subcontractors to fulfill their Part D contract. A related entity is a company that is related to the plan sponsor by common ownership or control. The subcontractors of plan sponsors may also subcontract.[5] For example, a plan sponsor might subcontract with a pharmacy benefit manager (PBM), and the PBM might subcontract with numerous pharmacies. Regardless of the number of subcontractors and related entities involved per plan sponsor, the plan sponsor is ultimately responsible for the Medicare contract requirements and all data submitted to CMS.[6]

Detecting and Deterring Fraud and Abuse

Plan sponsors are required to have a comprehensive program to detect and deter fraud and abuse.[7] The specifics of the program are left to the discretion of each plan sponsor. However, CMS provides fraud and abuse program guidelines for plan sponsors in chapter 9 of its "Prescription Drug Benefit Manual" (hereinafter CMS Manual).

Fraud and abuse reporting. CMS does not require plan sponsors to report statistics about fraud and abuse detection and deterrence other

[4] 42 U.S.C. § 1395w-115e.

[5] CMS refers to the subcontractors as first tier and downstream entities. CMS, "Prescription Drug Benefit Manual," v. 4-25-06, ch. 9, § 40.

[6] 42 CFR §§ 423.505(i) and 423.505(k).

[7] 42 CFR § 423.504(b)(4)(vi)(H).

than the quarterly aggregate number of fraud and abuse complaints that plan sponsors receive from beneficiaries. The requirement to report complaints is based on a Federal regulation that requires plan sponsors to keep track of enrollee grievances.[8] CMS uses the term "grievance" for beneficiary complaints to sponsors to distinguish them from beneficiary complaints that CMS receives from its complaint lines.[9] We will use the term "complaints from beneficiaries" or "beneficiary complaints" to refer to grievances in this report. Fraud and abuse is one of 11 categories of beneficiary complaints that plan sponsors report to CMS.

Plan sponsors must report to CMS the number of beneficiary complaints they receive for each plan. CMS's instructions state that because plan sponsors must maintain certain information about the enrollee regarding each complaint, plan sponsors should be able to report the data by plan.[10]

CMS defines fraud and abuse complaints as follows:

- A fraud complaint is an allegation that a person or an entity (e.g., beneficiary, provider, or plan) engaged in an intentional deception or misrepresentation that they know or believe to be false and that they know could result in some unauthorized benefits.
- An abuse complaint is an allegation that a person or an entity (e.g., beneficiary, provider, or plan) engaged in behavior that they should have known to be false and that could result in some unauthorized benefits.

Internal and external sources of information about potential fraud and abuse. Plan sponsors can identify potential fraud and abuse through internal efforts, such as claim reviews and subcontractor audits.[11]

Plan sponsors can also identify potential fraud and abuse through complaints they receive from external sources. External sources include

[8] 42 CFR § 423.564(g).

[9] CMS, "CY 2007 Part D Reporting Requirements: Frequently Asked Questions."

[10] Ibid.

[11] CMS, "Prescription Drug Benefit Manual," v. 4-25-06, ch. 9, §§ 50.2.6.1–50.2.6.3.

CMS, Medicare Drug Integrity Contractors (MEDIC), law enforcement agencies, beneficiaries, and pharmacy providers.

In this report, when we use the phrase "complaints from external sources," we mean all fraud and abuse complaints or referrals made to plan sponsors, including those from beneficiaries.

Inquiries into potential fraud and abuse. Plan sponsors are required to conduct a timely, reasonable inquiry (i.e., preliminary investigation) when evidence suggests potential fraud or abuse related to payment or delivery of Part D prescription drug items or services.[12] CMS recommends that the inquiry be initiated no later than 2 weeks from the date the incident is identified. In the event that the plan sponsor does not have time or resources to investigate the incident, CMS recommends that plan sponsors refer the incident to a MEDIC within 2 weeks from the date the incident is identified. MEDICs will further investigate referrals from plan sponsors and make referrals to law enforcement agencies when necessary.[13] MEDICs are responsible for assisting CMS with Part D audits, oversight, and antifraud and abuse efforts.

Corrective actions. In response to potential fraud and abuse, plan sponsors are required to carry out appropriate corrective actions (e.g., repayment of overpayments and disciplinary action against responsible individuals).[14]

Referrals to Government entities for further investigation. CMS recommends that after conducting inquiries, if plan sponsors identify potential fraud or abuse, they should refer the incidents to a MEDIC for further investigation. CMS recommends that the referral be made within 2 months of determining that fraud or abuse may have occurred.[15]

CMS also recommends that plan sponsors voluntarily report potential fraud or abuse discovered at the level of the plans, subcontractors, or sponsor-related entities to law enforcement entities, such as the Office

[12] 42 CFR § 423.504(b)(4)(vi)(G)(1).

[13] CMS, "Prescription Drug Benefit Manual," v. 4-25-06, ch. 9, § 50.2.8.3.

[14] 42 CFR § 423.504(b)(4)(vi)(G)(2).

[15] CMS, "Prescription Drug Benefit Manual," v. 4-25-06, ch. 9, § 50.2.8.2.

of Inspector General (OIG) (through OIG's Provider Self-Disclosure Protocol) or the Department of Justice.[16] [17]

Plan sponsors can also make referrals for further investigation to other Government entities, including CMS, State agencies, and local law enforcement agencies.

Related Study by the Office of Inspector General

In December 2006, OIG issued a report entitled "Prescription Drug Plan Sponsors' Compliance Plans" (OEI-03-06-00100). In this study, OIG found that of 79 compliance plans for stand-alone drug plan sponsors:

- 14 did not indicate that the sponsors had any procedures in place to identify fraud and abuse;
- 19 did not indicate that the sponsors had procedures to voluntarily report fraud or misconduct to Government entities, such as OIG or the Department of Justice;
- 43 did not describe procedures for responding to compliance violations; and
- 54 did not provide detailed descriptions of the types of corrective actions sponsors undertake in response to compliance violations.

METHODOLOGY

Scope

We reviewed Medicare Part D stand-alone drug plan sponsors' fraud and abuse information for the first 6 months of 2007. During this period, there were 91 such plan sponsors across the country and in U.S. territories. However, our study includes 86 plan sponsors with a total of 2,039 plans.[18] We did not include five plan sponsors because one had

[16] Ibid. In December 2007, CMS issued a final rule retaining plan sponsors' voluntary self-reporting of potential fraud or misconduct. However, in the publication of the rule, CMS stated that it is committed to adopting mandatory self-reporting and was seeking additional comments to craft a mandatory provision. 72 Fed. Reg. 68700, 68707 (Dec. 5, 2007).

[17] OIG's Provider Self-Disclosure Protocol offers providers a method of coming forward to work openly and cooperatively with OIG to quantify a particular problem and ultimately to promote a higher level of ethical and lawful conduct throughout the health care industry. 63 Fed. Reg. 58399 (Oct. 30, 1998).

[18] We did not include employer/union groups that contract directly with CMS in this study. However, some plan sponsors in our study provided national or regional plans to employer/union groups. These plans are included in our study.

been terminated from the program, one was under investigation, and three did not respond to our data request in time to be included in our review.

Of the 2,039 plans in our review, 1,332 were also offered to beneficiaries in 2006. For these 1,332 plans, we also collected data for the last 6 months of 2006.

Data Collection

Plan sponsors. We sent a data request to each plan sponsor that was on file in CMS's Health Plan Management System as of October 2007. We requested that the plan sponsors send us data regarding each of their plans.

Thirteen plan sponsors in our study did not provide data by plan as we requested. These plan sponsors stated that they do not track their data at that level. Eight of these plan sponsors provided their data aggregated to the plan sponsor level. The other five plan sponsors provided data for each State and/or U.S. territory where their plans were offered.

For the first 6 months of 2007 and, if applicable, the last 6 months of 2006, we asked each plan sponsor to provide the number of potential fraud and abuse incidents identified through internal efforts and the number of complaints received from external sources as defined by CMS. These external sources include CMS, MEDICs, law enforcement agencies, beneficiaries, and others. We also asked for the number and types of fraud and abuse identified, the number and types of persons or entities associated with the fraud and abuse incidents identified, the number of inquiries conducted, the number and types of corrective actions initiated as a result of the fraud and abuse identified, and the number of referrals for further investigation made to Government entities.

Centers for Medicare & Medicaid Services. We collected information about the plan sponsors from CMS's Part D enrollment files and Health Plan Management System. We collected the number of plans offered, regions covered, and beneficiaries enrolled.

Analysis

For all plan sponsors in our study, we summarized responses for each question in our data request at the plan sponsor level. For the 73 plan sponsors that provided data by plan, we also summarized responses for each question at the plan level. We summarized data by State and U.S.

territory for respondents that provided the data by those variables. We identified the mean, median, maximum, and minimum for each question.

We also compared plan sponsors' responses based on the number of plans offered, regions covered, and beneficiaries enrolled.

For plan sponsors that provided data for the last 6 months of 2006, we compared those data with data from the first 6 months of 2007. However, we did not include the 2006 information in this report because it was not significantly different from the 2007 data.

We assigned an identification number to the plan sponsors in our review based on the number of potential fraud and abuse incidents they identified through internal efforts. We use these identification numbers in all of our report tables so that the reader can identify information related to the same plan sponsor across the different tables.

Our findings that plan sponsors identified or did not identify potential fraud and abuse incidents are based on the numeric data that plan sponsors provided.

Limitations

We did not independently verify the information plan sponsors provided to us or to CMS's Health Plan Management System.

We use the term "incident" (i.e., potential fraud and abuse incident) to represent an instance of misconduct or a violation, not the number of providers involved in the misconduct or violation. However, in our analysis of plan sponsor responses, we saw that the numbers plan sponsors provided for certain questions about fraud and abuse volume did not always match. One example was a plan sponsor that reported identifying a total of 92 incidents of potential fraud and abuse from internal and external sources but conducted only 46 inquiries. Another example was a plan sponsor that reported identifying a total of 66 incidents of potential fraud and abuse but initiated 171 corrective actions. We did not determine why this information did not match.

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.

FINDINGS

Overall, 24 of 86 Part D stand-alone plan sponsors did not identify any potential fraud and abuse incidents; most potential fraud and abuse incidents were associated with only a small number of plan sponsors

Twenty-four plan sponsors (28 percent) did not identify any incidents of potential fraud and abuse, either from internal efforts or complaints from external sources, in the first 6 months of 2007. Sixty-two plan sponsors (72 percent) identified a total of 9,774 potential fraud and abuse incidents in this time period. Of these 62 plan sponsors, the number of incidents per plan sponsor ranged from 1 to 6,533, with a median of 11. Plan sponsors are not required to report to CMS the number of fraud and abuse incidents they identify, only the number of beneficiary complaints they receive.

Most of these potential fraud and abuse incidents were associated with seven plan sponsors. As shown in Table 1, these seven plan sponsors represent 90 percent of the total number of potential fraud and abuse incidents (8,817 of 9,774). One of these seven plan sponsors identified 67 percent of the incidents. Although these seven plan sponsors identified most of the potential fraud and abuse incidents, only two of the seven are among the top seven plan sponsors with the largest beneficiary enrollment. Appendix A provides the number of potential fraud and abuse incidents identified and other information for 86 plan sponsors.

Table 1. Top Seven Plan Sponsors That Identified the Most Potential Fraud and Abuse Incidents, First 6 Months of 2007

Plan Sponsor ID	Number of Potential Fraud and Abuse Incidents	Percentage of All Potential Fraud and Abuse Incidents[1]	Number of Plans Offered	Number of Regions Covered[2]
1	6,533	67%	104	34
33	860	9%	104	34
2	636	7%	107	35
14	258	3%	104	34
3	242	2%	2	1
10	166	2%	41	34
5	122	1%	101	33
Total	8,817	90%		

Sources: CMS's Health Plan Management System data and OIG analysis of plan sponsor responses.
[1] Percentages are affected by rounding.
[2] National employer/union group plans are not included in this column.

Plan sponsors identified 78 percent of all potential fraud and abuse incidents through internal efforts; however, 42 plan sponsors did not identify any potential fraud and abuse through internal efforts

Of the 9,774 incidents of potential fraud and abuse, 7,595 incidents (78 percent) were identified through internal efforts. An example of an internal effort is claim reviews. Forty-four plan sponsors (51 percent) identified potential fraud and abuse from internal efforts; 42 plan sponsors (49 percent) did not identify any potential fraud and abuse from internal efforts.

One plan sponsor was associated with 84 percent of the potential fraud and abuse incidents identified through internal efforts. As shown in Table 2, one plan sponsor was responsible for 84 percent of the potential fraud and abuse incidents identified through internal efforts (6,410 of 7,595 incidents). Table 2 also shows that this plan sponsor, along with two additional plan sponsors, made up 95 percent of the potential fraud and abuse incidents identified from internal efforts. Appendix A provides data on all plan sponsors' internal efforts.

Table 2. Top Three Plan Sponsors With the Most Potential Fraud and Abuse Incidents Identified Through Internal Efforts, First 6 Months of 2007

Plan Sponsor ID	Number of Incidents Plan Sponsors Identified Through Internal Efforts	Percentage of All Incidents Plan Sponsors Identified Through Internal Efforts
1	6,410	84%
2	592	8%
3	242	3%
Total	7,244	**95%**

Source: OIG analysis of plan sponsor responses.

Twenty-two percent of potential fraud and abuse incidents identified came from external sources; however, 34 plan sponsors did not identify any potential fraud and abuse incidents from external sources

Of the 9,774 incidents of potential fraud and abuse identified by plan sponsors, 2,179 (22 percent) were complaints from external sources. Fifty-two plan sponsors (60 percent) had fraud and abuse complaints from external sources; 34 plan sponsors (40 percent) had no complaints from external sources. Of the 2,179 complaints from external sources, 80 were from law enforcement agencies, 936 were from CMS and MEDICs, and 1,163 were from beneficiaries and other sources such as pharmacy providers.

Two plan sponsors were associated with 51 percent of these incidents. Two plan sponsors had the majority (51 percent) of the complaints from external sources. Appendix A provides the number of potential fraud and abuse incidents identified through external sources for all 86 plan sponsors.

Inappropriate billing was the most prevalent type of potential fraud and abuse incident identified; pharmacies were associated with most of the potential fraud and abuse incidents

Plan sponsors identified 26 different types of fraud and abuse (both from internal efforts and complaints from external sources). Plan sponsors are not required to report to CMS the types of potential fraud and abuse they identify.

Of the 26 types of potential fraud and abuse, the most prevalent type was inappropriate billing, with 9,073 incidents. An example of inappropriate billing is submitting claims for drugs not provided.

The second most prevalent type of potential fraud and abuse identified by plan sponsors was providing false information, with 520 incidents. An example of providing false information is misrepresentation of a beneficiary's personal identity, eligibility, medical condition, or plan enrollment.

The third most prevalent type of potential fraud and abuse identified by plan sponsors was doctor shopping, with 400 incidents. "Doctor shopping" is the term used for consulting a number of doctors for the purpose of inappropriately obtaining multiple prescriptions for drugs.

Plan sponsors identified fewer than 152 incidents of each of the other 23 types of potential fraud and abuse. Appendix B provides the number and types of potential fraud and abuse reported by plan sponsors.

Plan sponsors reported that pharmacies/pharmacists were the entities most often associated with potential fraud and abuse incidents. Plan sponsors reported that pharmacies/pharmacists were associated with 9,852 incidents (92 percent).[19] Plan sponsors reported that beneficiaries

[19] The number 9,852 is higher than the 9,774 potential fraud and abuse incidents that plan sponsors identified. One possible explanation is that more than one person or entity was identified for each incident of potential fraud and abuse.

were associated with 591 incidents and sales or marketing brokers were associated with 124 incidents. Plan sponsors themselves were also listed as entities associated with potential fraud and abuse during this period. Table 3 shows the persons or entities plan sponsors reported as associated with potential fraud and abuse.

Table 3. Persons or Entities Associated With Potential Fraud and Abuse Incidents, First 6 Months of 2007

Person or Entity	Number of Incidents
Pharmacy/pharmacist	9,852
Beneficiary	591
Sales or marketing broker	124
Third party	82
Physician or other prescriber	56
Plan sponsor	44
PBM	6
Family member	5
Insurance agency/agent	3
Claims adjudicator	2
Drug manufacturer	1
Total	10,766[1]

Source: OIG analysis of plan sponsor responses.

[1] The number 10,766 is higher than the total number of potential fraud and abuse incidents that plan sponsors identified and higher than the aggregated number of different types of fraud and abuse they reported. One possible explanation is that more than one person or entity was identified for each incident of potential fraud and abuse.

Not all 62 plan sponsors that identified potential fraud and abuse incidents conducted inquiries, initiated corrective actions, or made referrals for further investigation

Three actions that plan sponsors can take after identifying potential fraud and abuse are conducting inquiries, initiating corrective actions, and referring incidents for further investigation. Plan sponsors are not required to report to CMS any data concerning the actions they take in response to potential fraud and abuse.

Of the 62 plan sponsors that identified potential fraud and abuse, 47 conducted inquiries, 32 initiated corrective actions, and 33 referred incidents to other entities for further investigation. Overall, 17 plan sponsors initiated all three actions, 21 initiated two actions, 19 initiated one action, and 5 did not initiate any of these actions. Appendix A provides inquiry, corrective action, and referral information for all plan sponsors.

Inquiries. Of the 62 plan sponsors that identified potential fraud and abuse, 47 conducted 1,904 inquiries during the review period.[20] Of these 1,904, one plan sponsor conducted 849 inquiries, or 45 percent. The top four plan sponsors conducted 72 percent of all these inquiries.

CMS recommends that plan sponsors refer fraud and abuse incidents to MEDICs when they do not have the time or resources to conduct inquiries. Of 15 plan sponsors that identified potential fraud and abuse incidents but did not conduct inquiries, none sent any incidents to MEDICs because of time or resource constraints.

Corrective actions. Of the 62 plan sponsors that identified potential fraud and abuse, 32 initiated 9,011 corrective actions.[21] The most frequent type of corrective action was repayment of overpayments, with 8,318 actions taken. One plan sponsor that initiated 71 percent of the corrective actions (6,410 of 9,011) used repayments to address 98 percent of its potential fraud and abuse incidents. The second most frequent type of corrective action initiated was termination from the network, with 476 actions taken. Table 4, on the next page, shows the number and types of corrective actions plan sponsors initiated and the number of sponsors that initiated each type.

Three plan sponsors initiated a significantly higher number of corrective actions compared to the total number of potential fraud and abuse incidents they identified. These three plan sponsors initiated 795, 479, and 171 corrective actions, respectively, although they identified only 70, 2, and 66 potential fraud and abuse incidents.

[20] One plan sponsor that had not identified any potential fraud and abuse during this period reported conducting one inquiry. Therefore, the total number of inquiries plan sponsors conducted during this time period is 1,905.

[21] Two plan sponsors that had not identified any potential fraud and abuse during this period each reported initiating one corrective action. Therefore, the total number of corrective actions that plan sponsors initiated during this time period is 9,013.

Table 4. Corrective Actions Initiated by Plan Sponsors, First 6 Months of 2007

Type of Correction Action	Number of Times Type Was Initiated	Number of Plan Sponsors That Initiated Each Type[1]
Repayment of erroneous payment or overpayment	8,318	20
Termination from network	476	14
Disciplinary action	158	8
Correction of data	16	4
Utilization monitoring	8	1
Premium or true out-of-pocket cost adjustment	6	1
Reverse processing of erroneous prescriptions	6	1
Oversight	2	1
Unidentified	21	4
Total	9,011	

Source: OIG analysis of plan sponsor responses.
[1]Column cannot be totaled because some plan sponsors are represented in more than one row.

Referrals. Of the 62 plan sponsors that identified potential fraud and abuse incidents, 33 made at least 1 referral for further investigation, for a total of 1,701 referrals.[22] The referrals were made to CMS, Department of Justice agencies, local law enforcement agencies, MEDICs, OIG, State agencies, and other plan sponsors. Eighty-nine percent of these referrals went to MEDICs (1,522 of 1,701). Two plan sponsors made 89 percent of the referrals to MEDICs (1,347 of 1,522).

[22] One plan sponsor that reported not identifying any potential fraud and abuse during this period also reported referring three incidents of potential fraud and abuse for further investigation. Therefore, the total number of referrals for further investigation during this time period is 1,704.

RECOMMENDATIONS

Plan sponsors are the first line of defense against Part D fraud and abuse. They are required to have a comprehensive program to detect and deter Part D fraud and abuse. However, we found that some of these plan sponsors did not identify any potential fraud and abuse incidents; most incidents were identified by a small number of plan sponsors; and not all plan sponsors that identified potential fraud and abuse conducted inquiries, initiated corrective actions, or made referrals for further investigation.

CMS does not routinely collect information that would describe the overall volume or types of Part D fraud and abuse that occur or other outcome-related information that would inform CMS as to the effectiveness of the comprehensive fraud and abuse plan each sponsor is required to have in place. The only information concerning fraud and abuse that CMS requires to be reported is the quarterly aggregate number of fraud and abuse complaints that plan sponsors received from beneficiaries. There is no required reporting to CMS of information relating to self-identified instances of fraud or allegations received from sources other than beneficiaries. Further, the data CMS collects about beneficiary complaints to plan sponsors do not provide information about whether, or how effectively, the plan sponsors addressed the allegations.

A crucial aspect of protecting the integrity of the Part D program is ensuring that the plan sponsors have in place a comprehensive and effective program to detect and deter fraud and abuse. Therefore, we recommend that CMS:

Review Part D plan sponsors to determine why certain sponsors have identified especially high or low volumes of potential fraud and abuse incidents.

Determine whether the Part D plan sponsors that identified potential fraud and abuse initiated inquiries and corrective actions as required by CMS, and made referrals for further investigation as recommended by CMS.

Require Part D plan sponsors to maintain and routinely report information related to the results of sponsors' fraud and abuse programs.
Such information should include, but not be limited to, the number and types of potential fraud and abuse incidents identified through internal efforts and external sources, the number of inquiries conducted into potential fraud and abuse, the number and types of corrective actions

initiated, the number of referrals for further investigation, and the types of agencies to which referrals were sent. Moreover, all categories of required information should be clearly defined to prevent misinterpretation and to ensure that information from different sources can be compared.

Use this required information to help determine the effectiveness of sponsors' fraud and abuse programs.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS stated that it is committed to combating fraud, waste, and abuse in the Part D program but that because of limited funding, it has not been able to perform as much direct oversight of the Part D sponsors' fraud, waste, and abuse efforts as it anticipated.

CMS questioned the validity of our report numbers and stated that incidents might include beneficiary misunderstandings, a sponsor's noncompliance, and incidents of potential fraud.

The data that we requested from sponsors were specifically about potential fraud and abuse incidents. We asked sponsors to provide us the number of potential fraud and abuse incidents that they identified through internal efforts and the number of potential fraud and abuse incidents that they identified through external sources (e.g., law enforcement agencies, MEDICs, providers, and beneficiaries). We used terms from two CMS sources: (1) the "Prescription Drug Benefit Manual," chapter 9, which provides guidance on fraud and abuse programs; and (2) the CMS instructions to sponsors for reporting beneficiary complaint numbers. We agree that potential fraud and abuse incidents should be further defined by CMS to ensure comparability of data across sponsors and this is included in our third recommendation.

In response to OIG's first recommendation, CMS stated that it agreed that the variability in the number of potential fraud and abuse incidents identified by sponsors is a concern. CMS will examine the data more closely by referring the findings to MEDICs for further investigation. CMS also stated that it intends to revise the reporting requirements to enhance the data collected and give sponsors more specific guidance on how to track and properly label incidents, e.g., as an education issue or a potential fraud issue.

CMS concurred with OIG's second recommendation and will refer the data in this report to MEDICs for further investigation.

Although CMS provided comments about OIG's third recommendation, CMS did not state whether it concurred. CMS did state that OIG's report would be useful when CMS initiates its Part D sponsor compliance plan audits. CMS stated that our report will help ensure that sponsors are conducting their own internal investigations and taking appropriate corrective actions. CMS did not address OIG's fourth recommendation.

CMS provided technical comments. CMS stated that the number of complaint categories in the Complaint Tracking Module should be 10 and not 11 as stated on page 3 of the report. We did not change the number of complaint categories because there is an 11th category in the Complaint Tracking Module ("Other").

CMS stated that our methodology would be improved by including information about enrollments. However, during a meeting with CMS about our findings, prior to the issuance of our draft report, CMS staff requested that OIG remove enrollment information from the tables in the report because they believed that readers could use it to identify sponsors. OIG has provided CMS with a crosswalk to identify sponsors in our report tables for further analysis or followup.

We ask that, in its final management decision, CMS more clearly indicate whether it concurs with our third and fourth recommendations and what steps, if any, it will take to implement them. The full text of CMS's comments is provided in Appendix C.

APPENDIX ~ A

The table below provides information about the 86 Part D stand-alone drug plan sponsors reviewed in this report. The information is sorted by the number of potential fraud and abuse incidents plan sponsors identified through internal efforts.

Selected Fraud and Abuse Activities for Stand Alone Drug Plan Sponsors, First 6 Months of 2007

Plan Sponsor ID	Number of Plans Offered	Number of Regions Covered[1]	Number of Potential Fraud and Abuse Incidents Identified Through Internal Efforts	Number of Potential Fraud and Abuse Incidents Identified Through External Sources[2]	Total Number of Potential Fraud and Abuse Incidents Identified	Number of Inquiries Conducted	Number of Corrective Actions Initiated	Number of Referrals to Other Entities for Further Investigation
1	104	34	6,410	123	6,533	0	6,410	0
2	107	35	592	44	636	30	565	6
3	2	1	242	0	242	242	154	0
4	2	1	37	3	40	0	20	0
5	101	33	33	89	122	122	10	16
6	107	31	30	62	92	46	0	46
7	4	1	27	0	27	0	27	0
8	85	38	22	44	66	51	171	18
9	104	34	21	49	70	65	795	827
10	41	34	20	146	166	166	0	0
11	5	1	15	3	18	17	0	2
12	2	1	13	0	13	5	0	8
13	56	33	12	27	39	20	0	0
14	104	34	9	249	258	18	14	38
15	5	1	9	2	11	11	0	2
16	2	1	9	1	10	10	7	4
17	70	34	8	24	32	0	8	11
18	69	21	8	17	25	10	0	0
19	17	1	7	9	16	8	0	8
20	4	1	7	1	8	8	0	0
21	5	1	6	0	6	6	0	8
22	5	1	5	10	15	14	1	6
23	110	36	4	88	92	19	0	4
24	68	33	4	73	77	2	0	6
25	92	34	4	13	17	17	17	0
26	3	1	4	3	7	7	10	0
27	1	1	4	0	4	4	0	3
28	4	1	4	0	4	4	0	4
29	15	3	3	16	19	19	11	6

Selected Fraud and Abuse Activities for Stand Alone Drug Plan Sponsors, First 6 Months of 2007 (continued)

Plan Sponsor ID	Number of Plans Offered	Number of Regions Covered[1]	Number of Potential Fraud and Abuse Incidents Identified Through Internal Efforts	Number of Potential Fraud and Abuse Incidents Identified Through External Sources[2]	Total Number of Potential Fraud and Abuse Incidents Identified	Number of Inquiries Conducted	Number of Corrective Actions Initiated	Number of Referrals to Other Entities for Further Investigation
30	42	12	3	10	13	5	0	0
31	4	2	3	5	8	0	0	0
32	2	1	3	3	6	0	0	1
33	104	34	2	858	860	849	209	624
34	2	1	2	10	12	12	2	8
35	6	1	2	5	7	6	6	3
36	3	1	2	0	2	0	479	0
37	2	1	2	0	2	2	2	0
38	68	34	1	59	60	0	57	3
39	3	1	1	11	12	12	1	23
40	104	34	1	5	6	5	1	3
41	67	33	1	4	5	3	3	3
42	5	1	1	3	4	4	1	1
43	5	1	1	0	1	0	2	1
44	3	1	1	0	1	1	0	0
45	4	1	0	34	34	32	0	3
46	14	7	0	14	14	14	0	0
47	9	1	0	13	13	1	13	0
48	3	1	0	10	10	10	8	0
49	4	1	0	7	7	7	0	0
50	4	1	0	4	4	0	0	0
51	2	1	0	4	4	3	0	0
52	4	1	0	4	4	4	0	0
53	56	24	0	3	3	3	1	0
54	6	2	0	3	3	3	3	2
55	3	1	0	3	3	3	0	0
56	4	1	0	2	2	2	2	2
57	2	1	0	2	2	2	0	0
58	2	1	0	2	2	0	0	0
59	4	1	0	2	2	0	0	0
60	4	1	0	1	1	0	1	0
61	4	1	0	1	1	0	0	1
62	1	1	0	1	1	0	0	0
63	33	10	0	0	0	0	0	0
64	36	34	0	0	0	0	0	0

Selected Fraud and Abuse Activities for Stand Alone Drug Plan Sponsors, First 6 Months of 2007 (continued)

Plan Sponsor ID	Number of Plans Offered	Number of Regions Covered[1]	Number of Potential Fraud and Abuse Incidents Identified Through Internal Efforts	Number of Potential Fraud and Abuse Incidents Identified Through External Sources[2]	Total Number of Potential Fraud and Abuse Incidents Identified	Number of Inquiries Conducted	Number of Corrective Actions Initiated	Number of Referrals to Other Entities for Further Investigation
65	3	1	0	0	0	0	0	0
66	4	1	0	0	0	0	0	0
67	4	1	0	0	0	0	0	0
68	5	1	0	0	0	0	0	0
69	5	1	0	0	0	0	0	0
70	37	35	0	0	0	0	0	0
71	4	1	0	0	0	1	1	3
72	6	3	0	0	0	0	0	0
73	4	1	0	0	0	0	0	0
74	9	1	0	0	0	0	0	0
75	10	5	0	0	0	0	0	0
76	2	1	0	0	0	0	0	0
77	4	1	0	0	0	0	0	0
78	2	1	0	0	0	0	1	0
79	4	1	0	0	0	0	0	0
80	4	1	0	0	0	0	0	0
81	3	1	0	0	0	0	0	0
82	2	1	0	0	0	0	0	0
83	3	1	0	0	0	0	0	0
84	4	1	0	0	0	0	0	0
85	4	1	0	0	0	0	0	0
86	3	1	0	0	0	0	0	0
Total	2,039		7,595	2,179	9,774	1,905	9,013	1,704

Sources: Centers for Medicare & Medicaid Services' Health Plan Management System data, and Office of Inspector General analysis of plan sponsor responses.

[1] There are 39 stand-alone drug plan regions. Of the 39, 25 include only one State, 9 include multiple States, and 5 include one U.S. territory each. The national employer/union group plans in our review are not included in the count of regions for this column.

[2] This column includes complaints that plan sponsors received from CMS, Medicare Drug Integrity Contractors, law enforcement agencies, beneficiaries, and others.

APPENDIX ~ B

Examples in this table came from the Centers for Medicare & Medicaid Services (CMS), "Prescription Drug Benefit Manual," chapter 9, sections 70.1 through 70.1.7; Medicare Drug Integrity Contractors' internal categories for complaints; and plan sponsor responses to our review questions.

Types of Potential Fraud and Abuse Identified by Stand-Alone Drug Plan Sponsors, First 6 Months of 2007

Type of Fraud and Abuse	Number of Incidents	Examples
Inappropriate Billing	9,073	• Billing for drugs or services not provided. • Billing multiple payers for the same prescriptions, except as required for coordination of benefit transactions. • Billing based on group visits, e.g., a pharmacist visits a nursing home and bills for numerous prescriptions without furnishing any specific service to individual patients.
Providing False Information	520	• Plan sponsor or subcontractor falsified information furnished to CMS. • Prescriber falsified information submitted through a prior authorization or other formulary oversight mechanism in order to justify coverage. • Misrepresentation of beneficiary's personal identity or eligibility information, medical condition, or plan enrollment information.
Doctor Shopping	400	• Beneficiary consulted a number of doctors for the purpose of inappropriately obtaining multiple prescriptions for narcotic painkillers or other drugs.
Attempting To Steal Beneficiary Identity/Money	151	• Beneficiary was asked for credit card or banking information. • Beneficiary was asked for payment over the telephone or Web. • Individual or organization posed as Medicare or Social Security with intent to steal beneficiary's identity or money.
Engaging in Improper Marketing Schemes	139	• Plan sponsor or subcontractor violated Medicare marketing guidelines or other Federal or State laws, rules, and regulations to improperly enroll beneficiaries in a Part D plan.
Overcharging Beneficiary	58	• Overcharging beneficiary for coinsurance or premium. • Pharmacy asked beneficiary to pay uncompensated amounts. • Bait and switch pricing, i.e., beneficiary is led to believe a drug will cost one price, but at point of sale beneficiary is charged a higher amount.

Types of Potential Fraud and Abuse Identified by Stand-Alone Drug Plan Sponsors, First 6 Months of 2007 (continued)

Type of Fraud and Abuse	Number of Incidents	Examples
Inappropriate Prescription Dispensing	50	• Dispensed expired or adulterated prescription drugs. • Dispensed drugs without a prescription. • Pharmacist or pharmacy benefit manager's (PBM) mail order pharmacy split prescription to receive additional dispensing fee.
Diverting Prescriptions	33	• Beneficiary obtained prescription drugs from a provider and gave or sold this medication to someone else. • Inappropriate consumption or distribution of a beneficiary's medications by a caregiver or anyone else. • Beneficiary resale of drugs on black market.
Providing Data That Lacks Integrity to CMS	27	• Submitted inaccurate or incomplete prescription drug event data or Part D plan quarterly data. • Improperly reported enrollment/disenrollment data to CMS to inflate prospective payments. • Inappropriately documented pricing information.
Forging/Altering Documents	27	• Prescriptions were altered by someone other than the prescriber or pharmacist with prescriber approval to increase quantity or number of refills. • Altered prescription, electronic claim records, medical document, etc., for greater payment.
Inappropriate Enrollment/ Disenrollment	26	• Beneficiary was dead at the time of enrollment. • Beneficiary enrolled under multiple plans. • Involuntary termination of enrollee for nonpayment of premium.
Engaging in Potential Drug Abuse	22	• Possible controlled substance abuse. • Outlier nonnarcotic; wasteful and potentially abusive drug use.
Billing the Wrong Person	8	• Wrong person charged for prescription.
Inappropriate Prescribing	7	• Off-label prescribing of controlled substance. • Prescriber is on Office of Inspector General's (OIG) Exclusion List.
Misusing Low-Income Subsidy	5	• Plan sponsor provided false or misleading information regarding the number of its members who applied and qualified for the low-income subsidy in order to receive unwarranted low-income subsidy payments. • Beneficiary not reimbursed by plan following retroactive low income subsidy determination. • Beneficiary not receiving the low-income benefit approved by CMS.

Types of Potential Fraud and Abuse Identified by Stand-Alone Drug Plan Sponsors, First 6 Months of 2007 (continued)

Type of Fraud and Abuse	Number of Incidents	Examples
Theft of Prescriber's Prescription Pad	5	• In context of e-prescribing, includes theft of provider's authentication, i.e., login, information, including Drug Enforcement Administration number.
Adverse Selecting	4	• Selected/denied beneficiaries based on illness profile or other discriminating factors.
Illegal Remuneration, Kickbacks, Bribes	4	• Prescriber was offered or paid, solicited, or received unlawful remuneration to induce or reward the prescriber to write prescriptions for drugs. • PBM received unlawful remuneration in order to steer a beneficiary toward a certain plan or drug. • Inappropriate discounts, support services, educational grants, and research funding.
Inappropriate Manipulation of True Out-of-Pocket Costs (TrOOP)	4	• Any manipulation/miscalculation of beneficiary's TrOOP to keep beneficiary in the coverage gap. • Plan sponsor did not correctly calculate amount beneficiary spent on prescription out of pocket. • Beneficiary manipulated TrOOP to push through the coverage gap to reach catastrophic coverage before being eligible.
Inappropriate Drug Formulary Decisions	3	• Plan sponsor, PBM, or PBM's pharmacy and therapeutics committees made decisions in which costs took priority over criteria such as clinical efficacy and appropriateness of formulary drugs. • Inappropriate formulary support activities such as inappropriate payments to PBMs, and formulary placement payments in order to have manufacturer's products included on a plan's formulary. • Bait and switch, i.e., frequent formulary changes to induce beneficiaries to sign up for specific drugs that are later removed.
Stockpiling	3	• Beneficiary attempted to game her/his drug coverage by obtaining and storing large quantities of drugs and then disenrolling, thus avoiding out-of-pocket costs, to protect against periods of noncoverage, or to sell drugs on black market.
Inappropriate Sales Technique by Manufacturer	2	• Manufacturer provided free samples to physicians expecting those physicians to bill Federal health care programs for the samples. • Illegal promotion of off-label drug usage through marketing, financial incentives, or other promotion campaigns. • Inappropriate marketing or promotion of drugs/products (sales, marketing, discounting) by manufacturer.
Prescribing Outside Scope of Practice	2	• Providers wrote prescriptions outside of their scope of practice.

Types of Fraud and Abuse Identified by Stand-Alone Drug Plan Sponsors, First 6 Months of 2007 (continued)

Type of Fraud and Abuse	Number of Incidents	Examples
Mass Prescribing	2	• Providers wrote prescriptions for drugs that were not medically necessary, often in mass quantities, and often for patients that were not theirs. These prescriptions were often written for controlled drugs for sale on the black market and might include improper payments to the provider. This practice is sometimes called a prescription mill.
Hiding/Siphoning Illegal Profits	1	• Arrangements by providers with pharmacies, PBMs, etc. to hide/siphon illegal profits.
Seeking Early Refills	1	• Beneficiary sought early refills.
Total	**10,577[1]**	

Source of numeric data: OIG analysis of plan sponsor responses.

[1] The number 10,577 is higher than the 9,774 potential fraud and abuse incidents that plan sponsors reported identifying from internal efforts and complaints from external sources. One possible explanation for the higher number is that more than one type of fraud and abuse was identified per incident.

APPENDIX ~ C

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: SEP 25 2008

TO: Daniel R. Levinson
Inspector General

FROM: Kerry Weems
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse," (OEI-03-07-00380)

Thank you for the opportunity to review and respond to this OIG draft report. The Centers for Medicare & Medicaid Services (CMS) appreciates the OIG's efforts in reviewing Part D Sponsors' fraud, waste, and abuse activities. CMS is committed to combating fraud, waste and abuse in the Part D program, and we are very concerned about the OIG's findings regarding the variability of the information reported by the Part D Sponsors. We are sharing this information with the Medicare Drug Integrity Contractors (MEDICs), so we can better understand this data. However, because of limited funds, we believe it is important to note that we have been unable to perform as much direct oversight of the Part D Sponsors' fraud, waste and abuse efforts as we anticipated. With additional funding, CMS would be able to perform more oversight of Part D Sponsors' compliance with CMS requirements. Because of the critical funding shortfall, CMS had to reprioritize its program integrity oversight activities. We made several requests for funding through an adjustment to discretionary spending totals, in fiscal year (FY) 2007 ($118 million) and FY 2008 ($183 million), and in each year Congress failed to enact our budget request. These requests would have allowed us to fully fund the MEDICs and conduct additional program integrity oversight activities.

Due to funding shortfalls, we chose to focus the MEDICs' efforts in the following four areas:

- Handling, assessing and investigating incoming complaints alleging fraud, waste and abuse in the Part D program. Between December, 2006 and May, 2008, the three MEDICs addressed approximately 3,595 complaints, conducted 1,343 investigations, referred 59 cases to law enforcement, and sent 54 immediate advisements to law enforcement;
- Establishing the MEDIC data infrastructure and operations. These activities included training the MEDICs on how to access and use Part D data for program integrity activities;
- Performing both proactive and reactive data analysis on Part D data as well as incoming complaint data. The MEDICs utilize their data resources for trending and vulnerability forecasting; and

- Processing law enforcement requests for information and providing guidance and technical assistance on Part D data and how to use these data to further an investigation.

CMS selected these activities because we believed this was the best and most efficient use of the limited funds we were allocated. We believe that these efforts have yielded successful results in identifying, preventing and fighting fraud, waste, and abuse in the Part D program, but we recognize that more must be done.

Because of the funding shortfall, to date, CMS has utilized incoming complaints as its primary tool in identifying, preventing and fighting fraud in the Part D Program. Through a careful and thorough triaging process, caseworkers, account/plan managers, and the MEDICs are able to resolve most incoming complaints. As a result of this triaging process, CMS is able to identify those complaints that are potential fraud. If the MEDICs substantiate evidence of potential fraud, the complaint becomes part of an investigation or case that is developed and referred to the appropriate law enforcement agencies.

CMS would like to express its concern over the methodology used by the OIG in this report. The numbers reported by the OIG were "rolled up" in such a way that CMS could not discern the breakout categories. There is an entire spectrum of incidents in the Part D Program - ranging from those stemming from beneficiary misunderstanding, a Sponsor's non-compliance, and incidents of potential fraud. Without properly categorizing the information reported by the Part D Sponsors, neither the OIG nor CMS can appropriately gauge the success of our current anti-fraud efforts or the level of potential fraud. The data that CMS currently requires does not accurately distinguish between beneficiary confusion and a Sponsor's non-compliance with Part D regulations and guidance and potential fraud. CMS intends to revise the reporting requirements to enhance the data collected. Specifically, CMS plans to provide the Sponsors with specific parameters to properly label any incidents (e.g., as an education issue, a compliance issue, or potential fraud). Once we are able to enhance this data collection requirement, CMS will have clearly defined data from which to perform oversight activities. As CMS enhances its data collection effort, we will use this data source along with our current complaint tracking of potential fraud issues to gain greater insight and understanding into a Part D Sponsor's fraud, waste, and abuse efforts.

CMS believes that it is important for the government to have information on potential fraud, waste, and abuse as soon as possible, but currently Part D Sponsors' reporting of potential fraud or potential misconduct is required only on a voluntary basis (see §423.504(b)(4)(vi)(G)(3)). A mandatory self-reporting requirement would address many of the OIG's concerns that are discussed in this report.

TECHNICAL FINDINGS

- The introduction discusses CMS fraud and abuse data collection from Sponsors. On page 3, the number of Complaint Tracking Module categories should be 10, not 11.
- The study methodology described on page 6 would be improved through the evaluation of the proportion of grievances to enrollment. This, in turn, would more accurately reflect grievance rates per enrollment. This would be particularly relevant for the 707 plans of the 2,039 plans included in the study that were new in 2007.

- On page 8, the study's findings are discussed. The wide range in the number of incidents and follow-up activities reported, as well as the inconsistencies in the data (such as the reported number of follow-up activities exceeding the number of incidents), suggests that Sponsors were not consistent in defining and reporting the terms associated with the reporting for the study. Thus, there is a strong indication that the validity and reliability of the reported data are fundamentally unproven and cannot be simply generalized to the larger population as the study contends.

OIG Recommendation
Review Part D plan Sponsors to determine why certain Sponsors have identified especially high or low volumes of potential fraud and abuse incidents.

CMS Response
We agree that the variability in the number of potential fraud and abuse incidents identified by Sponsors is a concern. As a result, we will examine this data more closely to better understand what is occurring by forwarding the findings to the MEDICs for further investigation. We also intend to revise the reporting requirements to enhance the data collected, so Sponsors will have more specific guidance on how we expect them to track and properly label any incidents (e.g., as an education issue, a compliance issue, or potential fraud). However, as stated previously, we are concerned about the validity of the numbers in this report.

OIG Recommendation
Determine whether the Part D plan Sponsors that identified potential fraud and abuse initiated inquiries and corrective actions as required by CMS and made referrals for further investigation as recommended by CMS.

CMS Response
We concur and will forward the findings to the MEDICs for further investigation.

OIG Recommendation
Require Part D plan Sponsors to maintain and routinely report information related to the results of sponsor's fraud and abuse programs.

CMS Response
This report will be useful as CMS initiates its Part D Sponsor Compliance Plan Audits. In September, 2008, the MEDICs will conduct a limited amount of desk audits of Part D compliance plans. In addition, as more MEDIC resources become available, CMS will continue to enhance our Part D program integrity efforts to include more audits, onsite reviews, and other more comprehensive fraud prevention activities. In addition, this report will assist us in ensuring that Sponsors are conducting their own internal investigations and taking appropriate corrective actions in response to those investigations.

CMS thanks the OIG for its efforts on this report. We look forward to continuing to work with OIG in the future to strengthen our oversight efforts and identify and prevent fraud, waste, and abuse in the Medicare Part D program.

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.

Isabelle Buonocore served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to the report include Conswelia McCourt; central office staff who contributed include Linda Abbott and Sandy Khoury.