Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE DRUG INTEGRITY CONTRACTORS' IDENTIFICATION OF POTENTIAL PART D FRAUD AND ABUSE

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EXECUTIVE SUMMARY

OBJECTIVE

(1) To determine the extent to which Medicare Drug Integrity Contractors (MEDIC) identified and investigated potential Part D fraud and abuse incidents and whether these incidents were identified through external sources or proactive methods.

(2) To describe any issues or barriers MEDICs encountered in identifying or investigating potential fraud and abuse incidents.

BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established Medicare Part D to provide prescription drug benefits under the Medicare program beginning January 1, 2006. As of February 2009, 27 million beneficiaries were enrolled in Part D plans. Total expenditures for Part D benefits were $49.5 billion in 2007.

Prior to implementing the Part D benefit, the Centers for Medicare & Medicaid Services (CMS) developed a strategy to help combat Part D fraud and abuse. One of the key aspects of this strategy was MEDICs' use of innovative techniques for data analysis. Beginning in fiscal year (FY) 2007, CMS awarded contracts to three regional MEDICs to address potential fraud and abuse related to the Part D benefit.

According to the MEDICs' Statement of Work and their individual task orders, MEDICs' responsibilities include, but are not limited to, identifying potential Part D fraud and abuse through external sources and proactive methods; fulfilling requests for information from law enforcement agencies; investigating potential Part D fraud and abuse; referring cases and making immediate advisements regarding potential Part D fraud or abuse to the Office of Inspector General (OIG); recommending appropriate administrative actions to CMS; identifying program vulnerabilities; and auditing the fraud, waste, and abuse programs that are part of plan sponsors' compliance plans. We reviewed MEDIC data covering FY 2008, the second year of MEDICs' operations.

FINDINGS

MEDICs identified 4,194 incidents of potential fraud and abuse and investigated 1,320 incidents; most incidents were identified through external sources rather than proactive methods. MEDICs identified

4,194 incidents of potential fraud and abuse in FY 2008. CMS's strategy for combating Part D fraud and abuse emphasized the importance of using new and innovative data analysis techniques. However, MEDICs identified 87 percent (3,641) of potential fraud and abuse incidents through external sources, primarily complaints, in FY 2008. The remaining 13 percent (553) of potential fraud and abuse incidents were identified through proactive methods, such as data analysis.

MEDICs conducted 1,320 investigations in FY 2008. Ninety-six percent of these investigations involved incidents of potential fraud and abuse identified through external sources. In addition, MEDICs made 65 referrals and 34 immediate advisements to OIG, made 257 referrals to State insurance commissioners, and made 39 referrals to CMS for administrative action in FY 2008.

Problems with accessing and using data hindered MEDICs' ability to identify and investigate potential fraud and abuse incidents.
MEDICs reported that they need both Part D prescription drug event (PDE) data and data regarding Medicare Part B to effectively identify and investigate instances of potential Part D fraud and abuse. However, MEDICs did not receive access to PDE data until August 2007, nearly a year after their contracts began. In addition, two MEDICs were not given access to Part B data until the fall of 2008, 2 years after their contracts began. The third MEDIC did not receive access to Part B data before its contract ended. Once they received access to PDE data, MEDICs reported that important variables were not part of the PDE data, making effective data analysis difficult. MEDICs also indicated that when they accessed PDE data, different types of prescriber identifiers were not stored in the correct fields, which affected the results of their data analysis.

MEDICs' lack of authority to directly obtain information from pharmacies, pharmacy benefit managers, and physicians hindered their ability to investigate potential fraud and abuse incidents.
MEDICs did not have the authority to directly obtain prescriptions and medical records from entities, such as pharmacies, pharmacy benefit managers, and physicians, in FY 2008. MEDICs reported that because CMS contracts with plan sponsors, MEDICs had the authority to request information only from the plan sponsors. MEDICs indicated that these restrictions hindered their ability to investigate incidents of potential fraud and abuse.

MEDICs may not have been aware of some potential fraud and abuse incidents because plan sponsors are not required to refer them. Plan sponsors are encouraged to refer potential fraud and abuse incidents to MEDICs but are not required to do so. One MEDIC stated it received relatively few referrals compared to the number of plan sponsors in its jurisdiction. The other two MEDICs indicated that while some plans referred incidents of potential fraud and abuse, other plans had never referred any such incidents.

CMS did not give MEDICs approval to conduct audits of plan sponsors' compliance plans in FY 2008. As outlined in the Statement of Work and their individual task orders, MEDICs are responsible for conducting audits of plan sponsors' compliance plans. However, none of these audits were conducted in FY 2008. All three MEDICs indicated that they were prepared to conduct compliance plan audits in FY 2008 but were not given approval by CMS to do so. Between October and December 2008, 2 years after MEDICs' regional contracts began, the two remaining MEDICs did receive approval from CMS to begin 10 audits of plan sponsors' compliance plans.

RECOMMENDATIONS

In 2005, prior to the start of the Part D program, CMS outlined a strategy in which innovative data analysis, conducted primarily by MEDICs, was one of the keys to combating Part D fraud and abuse. The Part D program is now in its fourth year, and while CMS has reprioritized its oversight activities since 2005 because of budget shortfalls, proactive data analysis remains an important tool in its efforts to fight Part D fraud and abuse.

Combating Part D fraud and abuse involves a number of key participants, including CMS, plan sponsors, and MEDICs. Previous OIG reviews have focused on plan sponsors' identification of fraud and abuse as well as CMS's oversight of the Part D program. All of these reviews identified vulnerabilities in the efforts to combat Part D fraud and abuse. For example, one OIG review found that a quarter of plan sponsors did not identify any incidents of potential fraud and abuse. Another OIG review found that CMS had not conducted any significant data analysis for fraud detection purposes and had relied largely on complaints to identify potential fraud and abuse.

Our current review found that during their second year of operations, MEDICs identified most incidents of potential fraud and abuse through

external sources, such as complaints, rather than proactive methods. In addition, various problems have hindered MEDICs' ability to identify and investigate potential fraud and abuse incidents. Also, CMS did not give MEDICs approval to conduct compliance plan audits in FY 2008. CMS's strategy was intended to combat fraud and abuse, partially through data analysis. However, MEDICs reported that barriers hindered their ability to consistently conduct comprehensive data analysis to detect and prevent potential fraud and abuse.

Therefore, we recommend that CMS:

Ensure MEDICs have access to accurate and comprehensive data to assist them in identifying and investigating potential fraud and abuse and conducting proactive data analysis.

Authorize MEDICs to directly obtain information that they need to identify and investigate potential fraud and abuse from entities, such as pharmacies, pharmacy benefit managers, and physicians. We recognize that implementing this recommendation may require statutory or regulatory change.

Require plan sponsors to report all potential fraud and abuse incidents that are referred to law enforcement agencies to MEDICs as well. If plan sponsors refer potential fraud and abuse to law enforcement agencies, they should also share this information with MEDICs to help MEDICs identify fraud and abuse trends and target problem providers.

Ensure MEDICs have approval to conduct compliance plan audits that they are responsible for under their task orders and Statement of Work. While MEDICs did not have CMS's approval to conduct compliance plan audits in FY 2008, they did receive approval to conduct 10 of these audits in early FY 2009. CMS should make approval of additional compliance plan audits a priority in the future.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with three of our four recommendations. CMS stated that it is committed to ensuring that its contractors have access to the information they need to identify, prevent, and fight Part D fraud.

CMS concurred with our first recommendation regarding MEDICs' access to data; however, it did not provide a timeframe for implementation. CMS did not indicate whether it concurred with our

second recommendation. Instead, CMS stated that it recognizes the value of the recommendation but that its statutory authority to collect information directly from downstream entities is limited. We acknowledge in our recommendation that statutory or regulatory change may be needed and we encourage CMS to seek these changes. CMS concurred with our third recommendation; however, CMS stated that it currently does not have the regulatory basis to require that plan sponsors report these incidents. We disagree and believe current regulations give CMS the ability to require that MEDICs be provided with such reports. CMS concurred with our fourth recommendation; however, it did not provide details on the number of compliance plan audits it would conduct.

We ask that CMS, in its final management decision, more clearly indicate whether it concurs with our second recommendation and what steps, if any, it will take to implement both our second and third recommendations. In addition, we ask that CMS provide more detail regarding its implementation of our first and fourth recommendations.

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INTRODUCTION

OBJECTIVE

(1) To determine the extent to which Medicare Drug Integrity Contractors (MEDIC) identified and investigated potential Part D fraud and abuse incidents and whether these incidents were identified through external sources or proactive methods.

(2) To describe any issues or barriers MEDICs encountered in identifying or investigating potential fraud and abuse incidents.

BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established Medicare Part D to provide prescription drug benefits under the Medicare program beginning January 1, 2006.[1] As of February 2009, 27 million beneficiaries were enrolled in Part D plans.[2] Total expenditures for Part D benefits were $49.5 billion in 2007.[3]

Medicare Drug Integrity Contractors

Prior to implementing the Part D benefit, CMS developed a strategy to help combat Part D fraud and abuse. One of the key aspects of this strategy was MEDICs' use of innovative techniques for data analysis. Beginning in fiscal year (FY) 2007, CMS awarded contracts to three regional MEDICs to address potential fraud and abuse related to the Part D benefit.[4]

MEDICs received $11.6 million in FY 2008 to carry out their contracted responsibilities. The three regional MEDICs and their contract payments for FY 2008 were:

- MEDIC West–Science Applications International Corporation, $4.1 million;

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

[2] Centers for Medicare & Medicaid Services (CMS), "Monthly Contract Summary Report," February 2009. Available online at http://www.cms.hhs.gov/MCRAdvPartDEnrolData/MCESR/list.asp#TopOfPage. Accessed on February 27, 2009.

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

[4] In FY 2006, MEDIC Southeast was awarded a national contract to monitor fraud and abuse related to Part D enrollment and eligibility issues. In FY 2007, MEDIC Southeast became a regional MEDIC.

- MEDIC North–SafeGuard Services, $3.8 million; and
- MEDIC Southeast–Health Integrity, $3.7 million.

As of September 2008, MEDIC West's jurisdiction covered 21 States and 9.6 million beneficiaries,[5] MEDIC North covered 27 States and 11.7 million beneficiaries, and MEDIC Southeast covered 8 States and 5.9 million beneficiaries. MEDIC West's contract was not renewed when it ended in September 2008. CMS transitioned the responsibility for the States and beneficiaries in MEDIC West's jurisdiction to the two remaining MEDICs during October and November 2008.

MEDICs' responsibilities are detailed in the "MEDIC Statement of Work" and individual task orders issued to each MEDIC. [6] According to the Statement of Work, MEDICs' responsibilities include, but are not limited to:

- identifying potential Part D fraud and abuse through external sources and proactive methods;
- fulfilling requests for information from law enforcement agencies;
- investigating potential Part D fraud and abuse;
- referring cases and making immediate advisements regarding potential Part D fraud or abuse to the Department of Health and Human Services Office of Inspector General (OIG);
- recommending appropriate administrative actions to CMS;
- identifying program vulnerabilities; and
- auditing the fraud, waste, and abuse programs that are part of plan sponsors' compliance plans.

Individual task orders include these responsibilities as part of the activities each MEDIC is required to perform.

Types of Fraud and Abuse

According to the Statement of Work, fraud is the intentional deception or misrepresentation that an individual makes, knowing it to be false, that could result in some unauthorized benefit to himself/herself or

[5] MEDIC jurisdictions include all 50 States, U.S. territories, and the District of Columbia (hereinafter referred to as States).

[6] CMS, "MEDIC Statement of Work," §§ 3.2 and 6.1.2, Rev. 2, September 28, 2007.

some other person.[7] Types of Part D fraud include, but are not limited to, billing for drugs or services not provided, altering prescriptions to obtain a higher payment amount, using another person's Medicare card to obtain prescriptions, and billing for brand-name drugs when generics are dispensed. Abuse involves behavior that an individual should have known to be false that could result in some unauthorized benefit. Examples of abuse include billing Medicare for services that are not covered or coding services incorrectly.

Fraud and Abuse Identification

MEDICs are required to identify potential fraud and abuse through both external sources and proactive methods.

External sources and proactive methods. Complaints are a primary external source of fraud leads. Fraud complaints may come directly to the MEDICs through the MEDICs' toll-free number, mail, and fax. MEDICs may receive complaints from Medicare beneficiaries, relatives, or other Medicare contractors. In addition, MEDICs may receive leads about potential fraud and abuse from other external sources, such as law enforcement agencies, Part D plan sponsors, or CMS.

Proactive techniques for identifying fraud can include analyzing claims data, conducting Internet searches to identify leads, and analyzing complaint data for trends. According to the Statement of Work, the MEDICs' ability to use innovative analytical methodologies is critical to the success of a benefit integrity program.[8] In addition, since the beginning of the Part D program, CMS has issued press releases emphasizing the importance of using new and innovative data analysis techniques to combat Part D fraud and abuse.[9] Proactive data analysis can enable MEDICs to identify indicators of potential fraud, such as duplicate billing or billing for drugs without an associated doctor visit.

Data sources. To identify potential fraud and abuse occurring in the Part D program, MEDICs are required to access and analyze different

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[7] Ibid., § 2.1.

[8] Ibid., § 6.2.

[9] CMS, "The New Medicare Prescription Drug Program: Attacking Fraud and Abuse," October 7, 2005. Available online at http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=1693. Accessed on March 18, 2009; CMS, "Medicare Finds Billions in Savings to Taxpayers," October 11, 2006. Available online at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=2030. Accessed on March 31, 2009.

kinds of data.[10] Specifically, MEDICs must access Part D prescription drug event (PDE) data. When beneficiaries fill prescriptions covered under Part D, their prescription drug plans must submit electronic summary records called PDE records to CMS. The PDE records contain Part D prescription drug cost and payment data. The PDE data are stored in a CMS database called the Integrated Data Repository. MEDICs are able to access this database using SAS programming software or through a software application called Cognos.

Medicare Part B claims are another important source of data for analysis. Part B claims include claims for physician services that provide information on a beneficiary's doctor visit and a beneficiary's diagnosis. This information can be used to determine whether a prescription has a corresponding office visit and whether a drug was prescribed appropriately.

According to the Statement of Work, MEDICs will have access to Medicare Part B, Part D, and other data, such as Medicaid and Medicare Part A, through an integrated system.[11] However, the full transition to this system is not expected to be complete until 2011. Until then, MEDICs must access data through individual systems.

Fraud and Abuse Investigation and Referral

MEDICs are required to investigate potential fraud and abuse and, when appropriate, refer potential fraud and abuse cases to OIG.[12] Cases referred to OIG may be accepted for investigation, returned to the MEDIC for further development, declined and referred to another law enforcement agency for investigation, or declined and referred back to the MEDIC for possible CMS administrative action.

Investigations. MEDICs are required to conduct investigations when they receive allegations of fraud from external sources or proactively identify potentially fraudulent situations. An investigation is the analysis performed to determine the facts and the magnitude of potential fraud. An investigation may include a review of a sample of PDE claims, beneficiary interviews, or a review of original prescriptions. MEDICs are required to consult with OIG to determine whether or not the investigation should be further developed for possible case referral to OIG.

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[10] CMS, "MEDIC Statement of Work," § 6.2, Rev. 2, September 28, 2007.

[11] Ibid., § 6.2.

[12] Ibid., § 6.1.2, § 6.5.1.

If an investigation does not result in a case referral or the case is not accepted by OIG, the MEDICs may refer the incident to CMS for administrative action. Administrative actions can include recovery of overpayments, suspension of payments, or imposition of civil monetary penalties. In addition, investigations involving insurance sales agents may result in referrals to State insurance commissioners who are responsible for licensing these agents.

Case referrals and immediate advisements. MEDIC investigations result in case referrals when the MEDIC has documented allegations that a provider, beneficiary, pharmacy, pharmacy benefit manager, or Part D plan has: (1) engaged in a pattern of improper prescription writing or billing, (2) submitted improper claims with actual knowledge of their falsity, or (3) submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity.[13]

Certain allegations are referred directly to OIG without a MEDIC investigation. These are called immediate advisements and include complaints by current or former employees of a suspected provider, Part D plan sponsor, or subcontractor; or involve entities that are the subject of ongoing OIG fraud investigations.

Medicare Drug Integrity Contractor Reporting Requirements

According to the Statement of Work, MEDICs are required to submit certain reports to CMS. One of these is a monthly referral log. MEDICs report their new case referrals and immediate advisements sent to OIG in this log as well as update the status of their previous referrals. The referral log also contains referrals MEDICs sent to State insurance commissioners.

In addition, MEDICs must submit quarterly reports to CMS on vulnerabilities identified within the Part D program during the previous quarter and possible ways to address them.

Previous Office of Inspector General Work

OIG has issued several reports regarding oversight of the Part D program. In October 2007, OIG issued a report that examined CMS's early implementation of safeguards against Part D fraud and abuse.[14] The report found that some safeguards were in place but that others,

[13] Ibid., § 6.5.

[14] OIG, "CMS's Implementation of Safeguards During Fiscal Year 2006 To Prevent and Detect Fraud and Abuse in Medicare Prescription Drug Plans," OEI-06-06-00280, October 2007.

such as data analysis to detect and prevent fraud and abuse, had not yet begun. The report also found that CMS relied largely on complaints to identify fraud and abuse and had not begun financial or compliance audits.

An October 2008 OIG report examined the extent to which Medicare Part D plan sponsors identified and took steps to address potential fraud and abuse in the first 6 months of 2007.[15] The report found that over a quarter of plan sponsors did not identify any incidents of fraud and abuse. The report also found that a few plan sponsors identified most incidents of potential fraud and abuse. Even those sponsors that identified potential fraud and abuse incidents did not always conduct inquiries or take corrective actions. Just two plan sponsors made 89 percent of all referrals of incidents to MEDICs.

Two OIG reports focused on plan sponsors' compliance plans. The first report, issued in December 2006, examined plan sponsors' compliance plans at the start of the Part D program.[16] The report found that few sponsors' plans met all of CMS's requirements or addressed all of the recommendations for the prevention, detection, and correction of fraud, waste, and abuse. The second report, issued in October 2008, examined CMS's oversight of plan sponsors' compliance plans.[17] OIG found that CMS conducted limited followup on the deficiencies that OIG had identified in its 2006 report, such as plan sponsors' lack of documented procedures for internal monitoring and auditing. CMS also did not conduct the routine compliance plan audits it originally had planned.

METHODOLOGY

Data Collection and Analysis

We collected data from each of the three MEDICs regarding FY 2008, the regional MEDICs' second year of operations.[18] We asked MEDICs

[15] OIG, "Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse," OEI-03-07-00380, October 2008.

[16] OIG, "Prescription Drug Plan Sponsors' Compliance Plans," OEI-03-06-00100, December 2006.

[17] OIG, "Oversight of Prescription Drug Plan Sponsors' Compliance Plans," OEI-03-08-00230, October 2008.

[18] In September 2008, MEDIC West's contract with CMS was not renewed. CMS transitioned the responsibility for the States in MEDIC West's region to the remaining two MEDICs during October and November 2008. We completed collecting data from MEDIC West before this transition was finalized.

for the number of incidents of fraud and abuse identified, investigations conducted, cases referred and immediate advisements made to OIG, referrals to State insurance commissioners, and administrative actions referred to CMS.[19] We also requested that MEDICs identify the external sources and proactive methods they used to identify potential fraud and abuse. In addition, we asked MEDICs to identify the types of potential fraud and abuse investigated and referred as cases or immediate advisements to OIG. We asked MEDICs to describe any issues or barriers they encountered in identifying or addressing potential fraud and abuse incidents. We reviewed this information to determine the extent to which MEDICs both identified potential fraud and abuse incidents and took action regarding such incidents.

From CMS, we obtained reports submitted by each of the MEDICs for FY 2008, including vulnerability reports and logs of case referrals, immediate advisements, and State insurance commissioner referrals. We reviewed this information to determine whether it corresponded with the information provided by the MEDICs as part of our data request. We also reviewed the vulnerability reports to determine whether the MEDICs identified any limitations in addressing Part D fraud and abuse.

After we reviewed the data from the MEDICs and the reports from CMS, we conducted onsite visits to each MEDIC to clarify and gain a better understanding of the information we received. We asked MEDICs for further information on their processes for identifying and addressing incidents of potential fraud and abuse. We also asked MEDICs to elaborate on any issues or barriers to identifying or addressing the potential fraud and abuse incidents described in their response to our data request. We compared this information with the vulnerability reports provided by CMS to identify any additional information on limitations in addressing Part D fraud and abuse.

Data collection was conducted between September 30 and December 18, 2008.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" approved by the Council of the Inspectors General on Integrity and Efficiency.

[19] We included follow-up education as an administrative action.

MEDICs identified 4,194 incidents of potential fraud and abuse and investigated 1,320 incidents; most incidents were identified through external sources rather than proactive methods

MEDICs identified 4,194 incidents of potential fraud and abuse in FY 2008. This represents 15 incidents of potential fraud and abuse for every 100,000 beneficiaries enrolled in Part D plans. Since the beginning of the Part D program, CMS has issued press releases emphasizing the importance of using new and innovative data analysis techniques to combat Part D fraud and abuse. However, in FY 2008, MEDICs identified most incidents of potential fraud and abuse through external sources rather than proactive methods.

Identification of potential fraud and abuse incidents. Eighty-seven percent (3,641) of the potential fraud and abuse incidents MEDICs identified in FY 2008 were identified through external sources. Complaints were the primary external source of potential fraud and abuse incidents MEDICs identified. Examples of other types of external sources included leads from plan sponsors, law enforcement, and CMS.

MEDICs reported that they identified the remaining 13 percent (553) of potential fraud and abuse incidents through proactive methods. Of the 553 potential fraud and abuse incidents identified through proactive methods, MEDICs identified 93 percent through data analysis. Examples of proactive analysis that MEDICs conducted included identifying high prescribers of certain drugs and identifying pharmacies with the highest Part D payments for prescription drugs. Other types of proactive methods included conducting Internet searches and reviewing media articles to identify leads.

MEDICs addressed incidents of potential fraud and abuse by conducting investigations, sending immediate advisements and case referrals to OIG, making referrals to State insurance commissioners, and making referrals to CMS for administrative action.

Table 1 shows the number and percentage of incidents identified and actions taken by the MEDICs and indicates whether the incidents involved were identified through external sources or proactive methods.

Table 1. Number and Percentage of Externally and Proactively Identified Incidents and Actions Taken by MEDICs in FY 2008

Incidents Identified and Actions Taken	External		Proactive		Total
	Number	Percentage	Number	Percentage	
Incidents Identified	3,641	87%	553	13%	**4,194**
Incidents Investigated[1]	1,270	96%	50	4%	**1,320**
Cases Referred to OIG[1]	52	80%	13	20%	**65**
Immediate Advisements to OIG	33	97%	1	3%	**34**
Referrals to State Insurance Commissioners[2]					**257**
Referrals to CMS for Administrative Action	39	100%	0	0%	**39**

Source: OIG analysis of MEDICs' responses to data request.

[1] Investigations and case referrals to OIG may have involved incidents identified prior to our FY 2008 timeframe.
[2] We did not ask MEDICs to indicate whether incidents referred to State insurance commissioners were identified through external sources or proactive methods.

Investigations. MEDICs conducted a total of 1,320 investigations of incidents of potential fraud and abuse in FY 2008. This represents five MEDIC investigations for every 100,000 Part D beneficiaries. The top three types of potential fraud and abuse investigated by MEDICs were marketing schemes (40 percent), drug diversion by beneficiaries (21 percent), and inappropriate prescribing (17 percent). Other types included theft of beneficiary identity or money and inappropriate billing. Ninety-six percent (1,270) of MEDICs' investigations involved incidents of potential fraud and abuse identified through external sources. Four percent (50) of investigations were based on incidents identified proactively.

Case referrals and immediate advisements. MEDICs referred 65 cases of potential fraud and abuse to OIG in FY 2008. This represents one case referral for every 500,000 beneficiaries enrolled in Part D plans.

Eighty percent of cases (52) referred to OIG involved incidents of potential fraud and abuse identified through external sources. Twenty percent (13) of case referrals involved incidents of potential fraud and abuse identified through proactive methods. One MEDIC was responsible for two-thirds of the referrals identified through proactive methods.

Case referrals involved different types of potential fraud and abuse. The three types referred most often were drug diversion by beneficiaries (29 percent), inappropriate prescribing (26 percent), and inappropriate billing (20 percent). Other types included theft of beneficiary identity or money and marketing schemes. Appendix A provides examples of the top five types of potential fraud and abuse investigated by MEDICs and referred to OIG in FY 2008.

Of the 65 cases referred to OIG, 63 percent (41) of cases were accepted. Another 28 percent (18) of referrals were declined by OIG but referred to another law enforcement agency. The remaining 9 percent (6) of referrals were either declined and referred back to the MEDIC for possible CMS administrative action, were returned to the MEDIC for further development, or were pending an OIG determination.

MEDICS made 34 immediate advisements to OIG in FY 2008. Sixty-two percent of these involved marketing schemes and another 15 percent involved inappropriate billing. Ninety-seven percent (33) of immediate advisements made to OIG involved potential fraud and abuse incidents identified through external sources. One immediate advisement involved a potential fraud and abuse incident identified through proactive methods.

State insurance commissioner referrals. MEDICs made a total of 257 referrals to State insurance commissioners in FY 2008. These referrals involved issues with insurance sales agents or brokers, such as deceptive marketing. We did not ask MEDICs to break out whether State insurance commissioner referrals involved incidents identified through external sources or proactive methods. However, MEDICs indicated that these referrals were based on incidents identified through beneficiary complaints, an external source.

Administrative actions. MEDICs made 39 referrals to CMS for administrative action in FY 2008. Eighty-five percent of these referrals involved education, such as education of plan sponsors, as the type of administrative action. MEDICs make referrals to CMS when a referral to law enforcement is not warranted. For example, a MEDIC received

numerous complaints about deceptive marketing practices by agents of a plan. In this instance, the MEDIC sent a referral to CMS to educate the plan sponsor on its responsibility for overseeing agents' marketing activities. All 39 referrals (100 percent) made to CMS for administrative action were based on incidents of potential fraud and abuse identified through external sources.

Problems with accessing and using data hindered MEDICs' ability to identify and investigate potential fraud and abuse incidents

MEDICs reported that they need both PDE data and data regarding Medicare Part B services to effectively identify and investigate instances of potential Part D fraud and abuse. However, all MEDICs reported problems with accessing and learning how to use PDE data and accessing Part B data.

Access to PDE data. The PDE data include information that identifies the beneficiary, pharmacy, prescriber, drug, and drug cost. MEDICs use PDE data to conduct proactive analysis to identify potential fraud and abuse, to investigate potential fraud and abuse incidents, and to fulfill requests for information from law enforcement agencies investigating cases. Issues with PDE data affected MEDICs ability to identify and investigate incidents of potential fraud and abuse. MEDICs did not receive access to PDE data until August 2007, nearly a year after their contracts began. MEDICs did have access to PDE data in FY 2008; however, all three reported that there were problems with accessing and learning how to use these data. The time spent learning how to access and use PDE data delayed MEDICs ability to fully use the data for analysis.

Access to important variables. MEDICs also reported that either PDE data do not include, or they cannot efficiently access, certain information that is vital to identifying and investigating potential fraud and abuse and building case referrals. For example, the MEDICs reported that PDE data do not include beneficiary demographic information, such as name and address. Law enforcement agencies also often ask for beneficiary information when they request information from the MEDICs. One MEDIC stated that not having this information available directly in the PDE makes fulfilling requests from law enforcement challenging. In addition, one MEDIC also noted that the beneficiary ZIP Code could not be accessed through the interface it uses to mine PDE information. This MEDIC explained that when using PDE

data in a mainframe environment, it could not access the beneficiary ZIP Code. The beneficiary ZIP Code could be accessed when using PDE data through the desktop application MEDICs use called Cognos. However, the MEDIC indicated that Cognos does not support complex data mining. Two MEDICs reported developing methods to circumvent barriers to accessing beneficiary address and ZIP Code information. However, MEDICs reported that not having this information readily available in the PDE data made conducting proactive data analysis to identify or investigate potential fraud and abuse incidents difficult.

Problems with prescriber identifiers in PDE data. MEDICs reported problems with using the PDE fields containing prescriber identifiers when accessing records through Cognos. MEDICs indicated that when they accessed PDE data using Cognos, different types of prescriber numbers were not stored in the correct fields, which affected the results of their data analysis. For example, one MEDIC reported that when using Cognos to query PDE data for records with a provider's National Provider Identifier (NPI) number, it found that NPI numbers were being stored in the field for Drug Enforcement Agency (DEA) numbers. As a result, no PDE records were identified when queries were run through Cognos using a prescriber's NPI number. The MEDIC addressed this issue by running queries with prescribers' NPIs against the DEA field. However, by the time this issue was identified, a number of case referrals had been sent to OIG and requests for information from law enforcement agencies had been completed. Therefore, the original information sent may not have included all of the records for a particular prescriber or his/her ranking among other prescribers may have been inaccurate.

Issues with tracking changes to PDE data. Two MEDICs also pointed out that PDE records may change over time and MEDICs cannot see the various iterations of a PDE record when they access PDE data. For example, if a plan sponsor identifies a pharmacy overpayment, it may correct the improper payment and adjust the PDE record. Once the adjustment is made, there is no record of the original payment amount in the PDE data that MEDICs access. This means that PDE data accessed at two different times may appear very different and there is no way to track the changes back to the original data without going to the plan sponsor for the claim. According to one MEDIC's vulnerability report, this missing information is vital to determining trends across multiple plans and to quantifying the amount of potential fraud for a particular pharmacy.

Access to Part B data. MEDICs need Part B data to conduct proactive data analysis and investigate potential Part D fraud and abuse incidents. For example, Part B data include diagnosis information, which may indicate whether a prescribed drug is appropriate. However, two MEDICs were not given access to Part B data until the fall of 2008, 2 years after their contracts began. The third MEDIC did not receive access to Part B data before its contract ended. One MEDIC stated that PDE data allow it to see only what drug was dispensed at the pharmacy and how much was paid. Having Part B data showing that the beneficiary had a corresponding doctor's visit would help MEDICs determine whether a prescription was appropriate.

MEDICs' lack of authority to directly obtain information from pharmacies, pharmacy benefit managers, and physicians hindered their ability to investigate potential fraud and abuse incidents

The ability to access information, such as hard copies of prescriptions and medical records, is important for conducting investigations and developing cases. According to the MEDICs, in FY 2008 they did not have the authority to directly obtain prescriptions or medical records from pharmacies, pharmacy benefit managers, and physicians. Federal regulations, effective in 2008, required plan sponsors and their related entities, contractors, and subcontractors to provide the Department of Health and Human Services and its designees with access to the books and records relating to the transactions under the plan sponsors' Part D contracts with CMS.[20] However, MEDICs reported that because CMS contracts with plan sponsors, MEDICs had the authority to request information only from the plan sponsors, not directly from first tier, downstream, and related entities, such as pharmacies and pharmacy benefit managers.[21] In addition, MEDICs indicated that they could not obtain medical records directly from physicians. One of the MEDICs reported that ideally it would conduct an investigation by requesting medical records from the physician to compare the diagnosis with the beneficiary's medication. The three MEDICs indicated that not being able to obtain

[20] 42 CFR § 423.505(i)(2)(i)(2008).

[21] First-tier, downstream, and related entities are generally entities that contract with plan sponsors. These entities are further defined at 42 CFR § 423.4. These entities were referred to in previous regulations as related entities, contractors, and subcontractors.

information directly from these entities was a barrier in investigating incidents of potential fraud and abuse.

New Part D regulations that took effect January 1, 2009, require that plan sponsors specify in their contracts with first tier, downstream, and related entities whether CMS or its agents (i.e., the MEDICs) may obtain information directly from these entities or whether the plan sponsor will provide the information.[22] However, if plan sponsors' contracts specify that information will be provided by them and not these entities, this will not address the MEDICs' problem with obtaining information directly. Additionally, this provision does not address MEDICs' authority to request medical records directly from physicians.

MEDICs may not have been aware of some potential fraud and abuse incidents because plan sponsors are not required to refer them

MEDICs' ability to identify potential fraud and abuse through external sources may have been hindered by a lack of referral requirements for Part D sponsors. Of the 3,641 incidents of potential fraud and abuse identified through external sources, 15 percent were referred by plan sponsors. However, MEDICs indicated that they may not have been aware of all incidents of potential fraud and abuse because plan sponsors are not required to refer such incidents to MEDICs, although they are encouraged to do so.[23]

Previous OIG work in this area indicates that few plan sponsors referred incidents to MEDICs.[24] One MEDIC stated it received relatively few referrals of potential fraud and abuse incidents compared to the number of plan sponsors in its jurisdiction. The other two MEDICs indicated that while some plans referred incidents of potential fraud and abuse, other plans had never referred any such incidents.

Plan sponsors may also report potential fraud or abuse to law enforcement agencies, such as OIG and the Department of Justice, without notifying the MEDICs. Therefore, MEDICs would not have

[22] 42 CFR § 423.505(i)(3)(iv).

[23] CMS, "Prescription Drug Benefit Manual," Pub. No. 100-18, ch. 9, § 50.2.8.2; 42 CFR § 423.504(b)(4)(vi)(G)(3).

[24] OIG, "Medicare Drug Plan Sponsors' Identification of Fraud and Abuse," OEI-03-07-00380, October 2008.

been aware of these incidents and, as a result, could have missed trends indicating problem providers or evidence of fraud schemes.

CMS did not give MEDICs approval to conduct audits of plan sponsors' compliance plans in FY 2008

Plan sponsors must have compliance plans with measures to detect, correct, and prevent fraud, waste, and abuse. These compliance plans must include certain elements, such as procedures for effective internal monitoring and auditing and procedures for ensuring prompt responses to detected offenses.

As outlined in the Statement of Work and their individual task orders, MEDICs are responsible for conducting audits of plan sponsors' compliance plans. However, none of these audits were conducted in FY 2008. All three MEDICs indicated that they were prepared to conduct compliance plan audits in FY 2008 but were not given approval by CMS to do so. One MEDIC indicated that it had the funds to begin the compliance plan audits but that CMS had not given approval to start conducting them.

Without compliance plan audits, there is no way to determine whether plan sponsors have these elements in place. Between October and December 2008, 2 years after MEDICs' regional contracts began, the two remaining MEDICs did receive approval from CMS to begin 10 audits of plan sponsors' compliance plans. As of June 2009, six of these audits had been completed.

RECOMMENDATIONS

In 2005, prior to the start of the Part D program, CMS outlined a strategy in which innovative data analysis, conducted primarily by MEDICs, was one of the keys to combating Part D fraud and abuse. The Part D program is now in its fourth year, and while CMS has reprioritized its oversight activities since 2005 because of budget shortfalls, proactive data analysis remains an important tool in its efforts to fight Part D fraud and abuse.

Combating Part D fraud and abuse involves a number of key participants, including CMS, plan sponsors, and MEDICs. Previous OIG reviews have focused on plan sponsors' identification of fraud and abuse as well as CMS's oversight of the Part D program. All of these reviews have identified vulnerabilities in the efforts to combat Part D fraud and abuse. One study found that a few plan sponsors identified most of the potential fraud and abuse incidents and a quarter identified none. Another study found that most plan sponsors' compliance plans did not meet all requirements. Two additional studies focused on CMS's oversight of the Part D program. One of these studies found that CMS conducted limited followup on the deficiencies that OIG had identified regarding sponsors' compliance plans. The other study found CMS had not conducted any significant data analysis for fraud detection purposes and had relied largely on complaints to identify potential fraud and abuse.

Our current review found that during their second year of operations, MEDICs identified most incidents of potential fraud and abuse through external sources, such as complaints, rather than proactive methods. In addition, MEDICs' ability to identify and investigate potential fraud and abuse incidents has been hindered by problems with accessing and using data, lack of authority to directly obtain information from certain entities, and limited referrals from plan sponsors. Also, CMS did not give MEDICs approval to conduct compliance plan audits in FY 2008 to determine whether plan sponsors' compliance plans included required measures to detect, correct, and prevent fraud, waste, and abuse. CMS's strategy was intended to combat fraud and abuse, partially through data analysis. However, MEDICs reported that barriers hindered their ability to consistently conduct comprehensive data analysis to detect and prevent potential fraud and abuse.

Therefore we recommend that CMS:

Ensure MEDICs have access to accurate and comprehensive data to assist them in identifying and investigating potential fraud and abuse and conducting proactive data analysis

CMS should work with MEDICs to identify what specific changes to the content or structure of PDE, Part B, or other data are needed to allow MEDICs to more readily conduct proactive data analysis and respond to requests from law enforcement.

Authorize MEDICs to directly obtain information that they need to identify and investigate potential fraud and abuse from entities, such as pharmacies, pharmacy benefit managers, and physicians

While we recognize that implementing this recommendation may require statutory or regulatory change, allowing MEDICs direct access to these entities is vital to their ability to effectively identify and investigate potential fraud and abuse.

Require plan sponsors to report all potential fraud and abuse incidents that are referred to law enforcement agencies to MEDICs as well

If plan sponsors refer potential fraud and abuse to law enforcement agencies, they should also share this information with MEDICs to help MEDICs identify fraud and abuse trends and target problem providers.

Ensure MEDICs have approval to conduct compliance plan audits that they are responsible for under their task orders and Statement of Work

While MEDICs did not have CMS's approval to conduct compliance plan audits in FY 2008, they did receive approval to conduct 10 of these audits in early FY 2009. CMS should make approval of additional compliance plan audits a priority in the future.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with three of our four recommendations. CMS stated that it is committed to ensuring that its contractors have access to the information they need to identify, prevent, and fight Part D fraud.

CMS concurred with our first recommendation and stated that it is building One PI, a system containing data on Part D, Part A, and Part B claims that MEDICs will have access to. CMS is confident that One PI will address the data concerns outlined in this report and will also facilitate proactive fraud identification efforts. However, CMS did not state when it expects MEDICs to have access to this system.

CMS did not indicate whether it concurred with our second recommendation. Instead, CMS stated that it recognizes the value of the recommendation but that its statutory authority to collect information directly from downstream entities is limited because of the structure of the Part D program. CMS stated that it will continue to search for alternatives to enhance its efforts in this area. We acknowledge in our recommendation that statutory or regulatory change may be needed and we encourage CMS to seek these changes.

CMS concurred with our third recommendation; however, CMS stated that it currently does not have the regulatory basis to require that plan sponsors report these incidents. We disagree and note that our recommendation does not require imposing mandatory self-reporting requirements on PDP sponsors; we only recommend that, to the extent such disclosures are made, CMS require them to also be reported to the MEDICs. We believe current regulations at 42 CFR § 423.504(b)(4)(vi)(G)(3), which provides that PDP sponsors should report fraud and abuse incidents "to CMS or its designee," give CMS the ability to require that MEDICs be provided with such reports.

CMS concurred with our fourth recommendation and acknowledged that there were delays in starting compliance plan audits. CMS stated that it has recently conducted a compliance plan audit of its largest Medicare Advantage and Part D contractor and that compliance plan audits will continue during FY 2009. However, CMS did not indicate how many compliance plan audits would be conducted in FY 2009 nor how many were planned for FY 2010.

We ask that CMS, in its final management decision, more clearly indicate whether it concurs with our second recommendation and what steps, if any, it will take to implement both our second and third recommendations. In addition, we ask that CMS provide more detail regarding its implementation of our first and fourth recommendations. The full text of CMS's comments is provided in Appendix B.

APPENDIX ~ A

Table A-1: Top Five Types of Potential Fraud and Abuse Investigated and Referred

Top Five Types of Potential Fraud and Abuse Investigated by Medicare Drug Integrity Contractors and Referred to the Office of Inspector General in Fiscal Year 2008	
Type of Fraud and Abuse	**Examples**
Drug Diversion by Beneficiaries	• Consulting a number of doctors to obtain multiple prescriptions. • Giving or selling prescribed medication to someone else. • Reselling drugs on the black market. • Forging or altering a prescription.
Inappropriate Billing	• Billing for drugs not provided. • Billing for brand-name drugs when generics are dispensed. • Billing for noncovered drugs as covered. • Billing multiple payers for the same prescription, except as required for coordination of benefit transactions. • Splitting prescriptions to receive additional fees.
Inappropriate Prescribing	• Writing prescriptions for drugs that are not medically necessary. • Misrepresenting dates and descriptions of prescriptions provided or the identity of the individual who provided the prescriptions.
Marketing Schemes	• Conducting unsolicited door-to-door marketing. • Enrolling a beneficiary without his/her permission. • Offering beneficiaries a cash payment to enroll in Part D. • Using unlicensed agents.
Theft of Beneficiary Identity/Money	• Asking a beneficiary for banking information over the telephone. • Individual or organization posing as a Medicare representative with intent to steal a beneficiary's identity or money. • Stealing beneficiary identification and using it to obtain drugs.

Sources: Office of Inspector General analysis of Medicare Drug Integrity Contractors' (MEDIC) response to data request and review of MEDICs' documentation; Centers for Medicare & Medicaid Services (CMS), "MEDIC Statement of Work," § 6.1.1, Rev. 2, September 28, 2007; and CMS, "Prescription Drug Benefit Manual," Rev. 2, April 25, 2006, ch. 9, § 70.

APPENDIX ~ B

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: AUG 20 2009

TO: Daniel R. Levinson
Inspector General

FROM: Charlene Frizzera /S/
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse" (OEI-03-08-00420)

Thank you for the opportunity to comment on the above-referenced OIG draft report. The Centers for Medicare & Medicaid Services (CMS) appreciates the OIG's efforts in reviewing the Medicare Drug integrity Contractors (MEDICs) identification of fraud, waste, and abuse among Part D sponsors. CMS is concerned about the risks that potential fraud poses to the Part D Program, and we have remedied some of the MEDICs data access issues. We are committed to ensuring that our contractors have access to the information they need to help us identify, prevent, and fight Part D fraud.

OIG Recommendation

Ensure MEDICs have access to accurate and comprehensive data to assist them in identifying and investigating potential fraud and abuse and conducting proactive data analysis.

CMS Response

The CMS concurs with this recommendation. CMS is currently building One PI, which is a data system that will give the MEDICs access to detailed data on all Part D claims, as well as Parts A and B claims. We are confident that One PI will address the data concerns outlined in this report as well as facilitate proactive fraud identification efforts.

OIG Recommendation

Authorize MEDICs to directly obtain information that they need to identify and investigate potential fraud and abuse from entities, such as pharmacies, pharmacy benefit managers, and physicians.

CMS Response

The CMS recognizes the value of this recommendation. Currently, CMS' statutory authority to directly contact downstream entities to obtain aggregate Part D information is limited due to the structure of the Part D program. However, we will continue to search for alternatives to enhance our efforts in this area. It is important to also note that CMS does not have contractual relationships with or regulatory oversight of physicians, pharmacists, or pharmacy benefit managers under the Part D benefit.

OIG Recommendation

Require plan sponsors to report all potential fraud and abuse incidents that are referred to law enforcement agencies to MEDICs as well.

CMS Response

The CMS concurs with this recommendation; however, we currently do not have the regulatory basis to require plan sponsors to report these incidents.

OIG Recommendation

Ensure MEDICs have approval to conduct compliance plan audits that they are responsible for under their task orders and Statement of Work.

CMS Response

The CMS concurs with this recommendation. We acknowledge that there was a delay in starting the compliance plan audits. CMS has recently conducted a compliance plan audit of its largest Medicare Advantage and Part D contractor. The compliance plan audits will continue during fiscal year 2009.

In addition, in an effort to strengthen our compliance oversight activities, CMS has restructured the MEDIC program for this upcoming contract year. One MEDIC will focus solely on compliance activities for the entire country. This MEDIC, the Compliance & Enforcement MEDIC, will be responsible for:

- Conducting compliance plan audits;
- Monitoring inappropriate agent/broker activity;
- Interfacing with the State Departments of Insurance;
- Investigating marketing violations; and
- Data trending and analysis of compliance issues.

The other MEDIC, the Benefit Integrity (BI) MEDIC, will concentrate on fraud, waste, and abuse efforts. Some of the BI MEDIC's responsibilities will include:

- Investigating potential fraud;
- Data and investigative analysis;
- Responding to Requests for Information from Law Enforcement;
- Conducting fraud audits;
- Referring potential fraud cases to Law Enforcement; and
- Providing support to Law Enforcement.

We expect that this specialization will reduce administrative barriers and allow CMS to leverage efficiencies, which will strengthen our compliance and fraud prevention efforts.

The CMS thanks the OIG for its efforts on this report, and we welcome the opportunity to continue our partnership with the OIG to address fraud in the 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.

Tara J. Bernabe 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 Nancy J. Molyneaux; central office staff who contributed include Rita Wurm.