

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**CMS'S IMPLEMENTATION OF  
SAFEGUARDS DURING FISCAL  
YEAR 2006 TO PREVENT AND  
DETECT FRAUD AND ABUSE  
IN MEDICARE PRESCRIPTION  
DRUG PLANS**



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October 2007  
OEI-06-06-00280

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## E X E C U T I V E   S U M M A R Y

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### OBJECTIVE

To determine the extent to which the Centers for Medicare & Medicaid Services (CMS) implemented safeguards during fiscal year (FY) 2006 to prevent and detect fraud and abuse in Medicare prescription drug plans (PDP).

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### BACKGROUND

CMS is responsible for safeguarding the Medicare Part D program against fraud and abuse. CMS is statutorily required to perform financial audits of PDPs contracted to provide drug benefits to Medicare beneficiaries. Beyond this requirement, CMS holds considerable discretion in structuring safeguards for the program. In total, we identified six major safeguard activities conducted by CMS: a complaint process, data-monitoring activities, financial audits, monitoring PDP sponsor compliance with contract requirements, oversight of PDP efforts to reduce fraud and abuse, and providing education and guidance to a number of stakeholders on fraud and abuse identification. CMS contracted with one Medicare Prescription Drug Integrity Contractor (MEDIC) in FY 2006 to perform some of these functions, including complaint investigation.

To identify the status of safeguard implementation and to provide an early assessment of progress, we reviewed documents provided by CMS and the MEDIC describing and documenting current and planned efforts during FY 2006 and conducted a series of structured interviews with CMS and MEDIC staff. Although our focus was on PDPs, some of the concerns raised may also be applicable to Medicare Advantage Prescription Drug Plans and the Retiree Drug Subsidy.

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### FINDINGS

**CMS implemented safeguard activities throughout FY 2006; however, further development or application of these activities is needed**

Some of CMS's safeguards have been functioning since enrollment began, while others were implemented in a limited capacity or had not yet begun. For example, the complaint process has been in place since

November 2005, but other safeguards, such as data analysis for fraud detection, had not yet begun by the end of FY 2006. Compliance audits, an important tool for monitoring PDP sponsor compliance, had not begun, but CMS staff underwent extensive preparations, including protocol development and staff training. CMS reported that initial preparation for financial audits began in FY 2006, with the first audits expected to begin in January 2008. CMS issued initial guidance for PDP compliance plans and is conducting education initiatives; however, the slow release of two important guidance documents raises concern.

**In FY 2006, CMS relied largely on complaints to identify potential fraud and abuse in the Medicare Part D program; however, not all complaints were investigated timely**

During the first year of the program's operation, CMS relied largely on complaints to identify potential fraud schemes and abusive practices. Fraud complaints are handled by the MEDIC, which evaluates the merit of each complaint, conducts investigations, and makes referrals to law enforcement, as appropriate. At the end of our data collection, 24 percent of the 6,132 complaints that the MEDIC had received were open cases, apparently the result of insufficient staff. In addition, CMS does not track Medicare Part D fraud and abuse complaints made to 1-800-MEDICARE, nor does it know if these callers actually follow through with instructions to make additional calls to the MEDIC hotline.

**Limits to legal authority, jurisdiction, and CMS's ability to monitor enrollees switching plans complicate CMS's efforts to safeguard Medicare Part D PDPs**

We identified three impediments to the effective oversight of Medicare Part D, specifically in the areas of financial auditing, Part D marketing, and utilization management. For example, CMS does not have the legal right to go onto the premises of pharmaceutical benefit managers to verify that plans accurately report all remuneration and must rely on PDP sponsors to include sufficient requirements in their own contracts. Further, CMS has limited authority over insurance brokers, one of the most frequent subjects of fraud complaints. Lastly, coordination of information between plans about beneficiaries suspected of inappropriate utilization had not occurred because the plan sponsors have concerns over the Health Insurance Portability and Accountability Act of 1996 privacy laws.

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## RECOMMENDATIONS

To ensure that CMS's program integrity safeguard activities are implemented in a manner that is sufficient to protect the Medicare Part D program, we recommend that CMS:

**Develop a comprehensive safeguard strategy for Medicare Part D PDPs with specific activities and target dates and ensure that all activities are progressing in a timely manner.** CMS should develop a comprehensive strategy with specific activities and target dates and assign staff to follow up on progress. Further, CMS should make Medicare Part D safeguard activities a sufficient priority in the budgeting process to support their timely and effective administration.

**Ensure that all fraud complaints receive proper attention.** CMS should have a process in place to monitor the number of open complaints and take action if backlogs occur. Additionally, CMS should investigate options to immediately transfer fraud complaints submitted to 1-800-MEDICARE to the appropriate MEDIC.

**Address legal concerns that may impede program integrity efforts.** Specifically, CMS should: (1) require PDP sponsors to include standard wording regarding requirements for record retention and accessibility within subcontractor contracts, (2) enforce appropriate sanctions for plans whose brokers violate permissible marketing practices, and (3) utilize the MEDICs as intermediaries for PDPs to share information about their beneficiaries suspected of inappropriate utilization.

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## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments to the draft report, CMS responded that many of its ongoing activities already satisfy our recommendations. It further stated that the report does not fully explain the immense workload required for CMS to develop and administer the benefit in its first year and indicated that processes and procedures have improved over time. CMS additionally reported several advances in this safeguard strategy that occurred after the end of our data collection period (FY 2006). We revised the draft report, as appropriate, based on these comments. CMS did not indicate whether it concurred with our recommendations. We ask that, in its final management decision, CMS indicate whether it concurs with our recommendations and what steps, if any, it will take to implement them.



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## OBJECTIVE

To determine the extent to which the Centers for Medicare & Medicaid Services (CMS) implemented safeguards during fiscal year (FY) 2006 to prevent and detect fraud and abuse in Medicare prescription drug plans (PDP).

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## BACKGROUND

This inspection is an early implementation review of CMS's efforts to prevent and detect fraud in Medicare Part D PDPs. A separate Office of Inspector General (OIG) inspection, "Prescription Drug Plan Sponsors' Compliance Plans," addressed efforts made by the plans themselves.<sup>1</sup>

### **Medicare Part D Prescription Drug Program**

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established the Medicare Part D prescription drug program. Effective January 1, 2006, this program provides an optional outpatient prescription drug benefit, which is available to all 42 million Medicare beneficiaries.<sup>2 3</sup> Beneficiaries generally have the option to enroll either in a stand-alone PDP for their drug coverage and receive all other benefits through traditional Medicare fee-for-service or enroll in a Medicare Advantage plan and receive all Medicare benefits, including drug coverage, through managed care.<sup>4</sup>

The MMA required an aggressive implementation schedule for the Medicare Part D benefit. In the approximately 2 years between passage of the law and the effective date of Medicare Part D coverage, CMS and plan sponsors were conducting implementation activities, including the development of procedures, data systems, and infrastructure to carry out all necessary functions. Applications for the first PDPs were due in March 2005 and beneficiaries began electing coverage in November 2005. As of July 2006, approximately 24 million Medicare

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<sup>1</sup> OEI-03-06-00100.

<sup>2</sup> Social Security Act § 1860D-1.

<sup>3</sup> Centers for Medicare & Medicaid Services, "Medicare Enrollment: National Trends 1966-2005." Available online at <http://www.cms.hhs.gov/MedicareEnRpts/Downloads/HISMI05.pdf>. Accessed on March 22, 2006.

<sup>4</sup> CMS, Final Rule, "Medicare Prescription Drug Benefit," 70 Fed. Reg. 4194 (January 28, 2005).

beneficiaries were enrolled in a Medicare Part D drug plan.<sup>5</sup> A summary of the benefit and its operation is included in Appendix A.

During 2006, the first full year of the benefit, expenditures totaled more than \$47 billion.<sup>6</sup> To implement the program, CMS received \$1 billion for startup costs to be used in FYs 2004 and 2005.<sup>7</sup> Of that \$1 billion, CMS used 44 percent for education and outreach, 5 percent for payroll expenses, and the balance primarily for information technology improvements.<sup>8</sup> It is unclear what portion of the \$1 billion was dedicated to program integrity efforts. In addition, CMS received a one-time increase of \$100 million from the Deficit Reduction Act (DRA) of 2005 for Medicare program integrity activities conducted during FY 2006.<sup>9</sup> A portion of these funds was allocated to activities designed to protect Medicare Part D from fraud and abuse. Future funding sources for Part D program integrity activities have yet to be determined.

#### **Program Integrity Staff and Medicare Prescription Drug Integrity Contractors**

Numerous groups within CMS have responsibility for overseeing aspects of Part D administration, including the Center for Beneficiary Choices, the Office of the Actuary, and the Office of Financial Management. However, the Medicare Modernization Act Integrity (MMAI) group within the Office of Financial Management's Program Integrity Group is focused specifically on fraud prevention and detection in Part D. The MMAI group conducts training, reviews regulations, and provides guidance to the Department of Health and Human Services on what fraud-related vulnerabilities exist and how they should be addressed. It is also responsible for overseeing the Medicare Prescription Drug Integrity Contractors (MEDIC).

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<sup>5</sup> Center for Medicare & Medicaid Services, "Medicare Advantage, Cost, PACE, Demo, and Prescription Drug Plan Contract Report – Monthly Summary Report." September 2006. Available online at [http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/02\\_EnrollmentData.asp](http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/02_EnrollmentData.asp). Accessed on October 18, 2006.

<sup>6</sup> "2007 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," p. 5. Available online at <http://www.cms.hhs.gov/ReportsTrustFunds/downloads/tr2007.pdf>. Accessed on July 24, 2007.

<sup>7</sup> Public Law 108-173 § 1015.

<sup>8</sup> Centers for Medicare & Medicaid Services, "Budget Facts." February 7, 2005. Available online at <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1350>. Accessed on May 30, 2006.

<sup>9</sup> Deficit Reduction Act § 5204 amending Social Security Act § 1817(k)(4)C.



MEDICs are private firms with which CMS contracts to perform fraud prevention and detection activities, including complaint tracking and investigation and data mining. Only one MEDIC contract was awarded for work conducted during FY 2006 and that contract was awarded on a reduced-scope basis. CMS attributed this decision to funding limitations. That MEDIC provided the staff dedicated to investigating prescription drug fraud complaints during the first year of the Medicare Part D benefit. Three regional MEDICs and a data-focused MEDIC were each awarded 1-year contracts in September 2006 (after release of the DRA funds) with operations beginning in December 2006.

### **Fraud and Abuse Strategy**

CMS is responsible for preventing and detecting fraud and abuse in Medicare Part D. However, the only activity statutorily required of CMS is to conduct financial audits of one-third of the plans each year.<sup>10</sup> Beyond that, CMS exercises considerable discretion in safeguarding the program. CMS's publicly announced plans to combat fraud and abuse in Medicare Part D include a range of prevention and detection activities; however, the complete strategy has not been laid out as a single comprehensive plan. Accordingly, we analyzed CMS's various press releases and guidance documents to identify CMS's safeguard activities.

In an October 2005 press release, CMS announced that it would be "expanding its efforts in fighting fraud and abuse in Medicare [Part D] by using state of the art systems and expertise to prevent problems before they occur."<sup>11</sup> It further discussed a general three-pronged approach to safeguarding the Medicare Part D program which includes: (1) implementing new and innovative techniques to monitor and analyze data to help identify fraud; (2) working with key partners, such as law enforcement and consumer groups; and (3) providing tips for beneficiaries to protect themselves. In this same press release, CMS announced the selection of eight MEDICs that would then be eligible to bid on contracts for future MEDIC work. Also in October 2005, CMS released a document titled "Part D Oversight Strategy for

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<sup>10</sup> Social Security Act § 1860D-12(b)(3)(C).

<sup>11</sup> CMS Fact Sheet: The New Medicare Prescription Drug Program: Attacking Fraud and Abuse. October 7, 2005. Available online at [www.cms.hhs.gov/apps/media/press/release.asp?Counter=1693](http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1693). Accessed on November 20, 2006.

Contractors/Industry.”<sup>12</sup> This document states that oversight “will be data driven to the extent possible” and identifies four functions that will feed into oversight: contractor management, auditing, compliance and enforcement, and the functions performed by MMAI and the MEDICs.

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## SAFEGUARD ACTIVITIES

We have defined safeguard activities as any activity or process that is able to prevent or detect fraud and abuse, as some activities identified as safeguards are not designed explicitly for that purpose. From CMS’s press releases, the oversight strategy document, and interviews with CMS staff, we identified the following six major types of safeguard activities:

- 1. Complaint Process**—This process involves the intake, tracking, and investigation of fraud complaints. Complaints may arise from beneficiaries, pharmacists, plan staff, or any other person with a fraud complaint pertaining to Medicare Part D. Complaints provide a source of direct information about potential fraud.
- 2. Data Monitoring**—Data monitoring describes the use of data systems to assess transactions and look for anomalies that might suggest fraud. This includes automated data edits, trend monitoring, and data mining.
- 3. Financial Audits**—Financial audits verify that plan-reported financial data are credible and accurate. The MMA specified that a financial audit should be conducted on one-third of all Medicare Part D plans each year. Financial audits could cover a wide range of topics and would potentially reveal problems that may result in overpayment to plans, including misrepresentation of bids, underreporting of rebates, and inaccurate prescription drug event data.
- 4. Monitoring PDP Sponsor Compliance**—CMS conducts a number of monitoring activities designed to oversee the operation of PDPs. If problems are identified through these activities, CMS can implement intermediate sanctions or terminate a PDP contract. The activities include account management activities, compliance audits, and operational safeguards.

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<sup>12</sup> Centers for Medicare & Medicaid Services, “Part D Oversight Strategy for Contractors/Industry.” October 24, 2005.

- *Account management*—CMS account managers act as a nerve center into which all types of PDP information feeds and are tasked with educating PDP sponsors on new, revised, or misunderstood policies. They hear complaints from the PDPs about CMS operations and receive regular reports about beneficiary complaints and PDP-reported data.
- *Compliance audits*—CMS staff use compliance audits to measure PDP sponsors' adherence to 14 broad elements that are required of them.<sup>13</sup> These audits are designed to ensure that plans have management controls in place to enable all necessary functions, including beneficiary enrollment and claims processing.
- *Operational Safeguards*—A wide range of management controls used in the routine operation of Medicare Part D have both a primary role in administration of the benefit and a secondary role of fraud prevention and detection. Two examples of operational safeguards are the bid review and the formulary and benefit review.<sup>14 15</sup>

**5. Oversight of PDP Efforts To Reduce Fraud and Abuse**—As part of the contract to administer PDPs, CMS requires PDPs to have in place effective fraud control programs and recommends some specific

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<sup>13</sup> The 14 elements addressed in the audit protocol are: (1) Enrollment and Disenrollment; (2) Provider Communication; (3) Marketing and Beneficiary Information; (4) Privacy and Confidentiality; (5) Drug Utilization Management, Quality Assurance, and Electronic Prescribing; (6) Pharmacy Access; (7) Formulary, Transition Process, and Pharmacy & Therapeutics Committee; (8) Medication Therapy Management; (9) Coordination of Benefits/True-Out-of-Pocket Costs; (10) Compliance Plan; (11) First-Tier and Downstream Contracts/Maintenance of Records; (12) Claims Processing and Payment; (13) Grievances, Coverage Determinations, and Appeals; and (14) Licensure and Solvency.

<sup>14</sup> The actuarial aspect of the bid review process is conducted by CMS's Office of the Actuary. CMS staff and contractors review bids to determine whether the assumptions underlying financial projections are appropriate and reasonable. Included in this review is a detailed statistical analysis to identify outlier values in the bid components. When outliers are identified, a more thorough review is initiated and values are substantiated prior to approval. Some specific aspects of the review may enable CMS to identify inappropriate cost manipulation tactics that could affect total Part D costs.

<sup>15</sup> CMS conducts a formal review to ensure that a PDP's formulary and benefit structure meet minimum specifications, ensuring that beneficiaries have access to a full range of medications. The formulary review process is an automated process that checks for these specifications. If the formulary does not pass the review, CMS returns the formulary to the plan for revision. A similar process is used to ensure that the plan's benefit package matches its formulary. For example, if a plan's benefit package indicates a certain number of cost tiers, the formulary must show drugs available in each of the tiers.

activities to identify potential fraud and abuse.<sup>16</sup> With the ability to monitor drug transactions and implement utilization controls that could serve as an alert for fraud, PDPs are uniquely situated to identify fraud committed by beneficiaries or pharmacies.

**6. Education and Guidance**—CMS has an initiative to educate beneficiaries about potential fraud schemes and how to protect themselves. Training for law enforcement, CMS staff, and other Government agencies is also designed to address fraud issues developing in Medicare Part D.

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## SCOPE

This review describes the implementation status of CMS safeguard activities related to stand-alone PDPs during FY 2006. We did not describe safeguard activities conducted by the PDPs themselves. As the prescription drug benefit is still new, we also did not seek to determine the effectiveness of the safeguards that are in place or planned. We also excluded issues of data integrity and security, which is being addressed by a separate OIG inquiry. Although our focus was on PDPs, some of the concerns raised may also be applicable to MA-PDs and the Retiree Drug Subsidy.<sup>17 18</sup>

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## METHODOLOGY

We reviewed a variety of documents and conducted a series of interviews with CMS and MEDIC staff to determine the implementation status of safeguard activities at the time of our review.

### Document Review

We reviewed publicly available documents as well as internal documents provided to us by CMS and the MEDIC. Documents included press releases, guidance documents, standard operating procedures, budget documents, contracts, and training materials.

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<sup>16</sup> 42 CFR § 423.504(b)(vi)(H).

<sup>17</sup> Medicare Advantage plans offer a complete range of health benefits including hospital and physician coverage. They may choose to offer an additional prescription drug benefit through Medicare Part D.

<sup>18</sup> The Retiree Drug Subsidy encourages private employers to provide Part D benefits to their retirees by subsidizing the cost for Medicare-eligible beneficiaries.

### **Interviews**

We conducted 19 interviews, either in person or by telephone, primarily during August and September 2006. These interviews were with CMS staff in the Office of Financial Management, the Center for Beneficiary Choices, and the Office of the Actuary. Our discussions addressed specific program integrity issues involved in various operations of the Medicare Part D program.

### **Site Visit**

We conducted a site visit with the Enrollment and Eligibility MEDIC, Delmarva Foundation, in Easton, Maryland. Delmarva Foundation was the only MEDIC in operation at the time of our data collection. During this visit, we interviewed managers and senior staff regarding their contracting process, operations, and perspectives on fraud vulnerabilities. Additionally, we observed the intake of beneficiary complaints to the MEDIC fraud hotline by telephone operators, toured the facility, and observed the use of the MEDIC's data systems. We also reviewed documentation of the complaint statistics, standard operating procedures, and training sessions conducted by MEDIC staff.

### **Direct Observation**

Several internal management systems were demonstrated for us by both CMS and the MEDIC. At CMS, we observed several modules of the Health Plan Management System (HPMS) in use, including bid review, formulary submission and review, plan benefit package review, and compliance audits.<sup>19</sup> During the MEDIC site visit we observed use of the Complaint Tracking Module of HPMS, as well as internal MEDIC complaint-tracking and data analysis systems. We also used the MEDIC's complaint-tracking data to determine the overall number of complaints.

### **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.

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<sup>19</sup> The HPMS is a Web-enabled information system that supports the ongoing operations of the Medicare Advantage and Part D programs by facilitating electronic communication between CMS and plans.

**CMS implemented safeguard activities throughout FY 2006; however, further development or application of these activities is needed**

Some aspects of CMS’s strategy to safeguard Medicare Part D have been operational since enrollment began in November 2005. Others were implemented in a limited

capacity or had not yet begun. Below are descriptions of each of the six safeguard activities, i.e., complaint process, data monitoring, financial audits, monitoring PDP sponsor compliance, oversight of PDP efforts to reduce fraud and abuse, and education and guidance, and their implementation status as of the end of FY 2006.

**Complaint Process—Complaint investigations resulted in 312 referrals related to the “\$299 Ring” scam and 122 other fraud referrals**

The process to handle complaints has been in place since November 2005. Generally, complaints are submitted through a public number (1-800-MEDICARE) and are routed to regional staff for followup and resolution. However, complainants that suggest fraud are advised to call to the MEDIC, which receives calls through a toll-free hotline number (1-877-7SAFERX) that is dedicated to complaints about potential Part D fraud. The MEDIC is responsible for evaluating the merit of fraud complaints and conducts investigations to determine whether referrals to law enforcement agencies or State insurance commissions are appropriate. Shortly after the end of the fiscal year, the MEDIC had investigated 1,421 complaints and made 434 fraud referrals.<sup>20</sup> Specifically, the MEDIC referred 38 cases to OIG, 80 cases to State insurance commissioners, and 4 cases to local or State law enforcement.<sup>21</sup> Additionally, the MEDIC referred 312 cases for a particular type of fraud, known as the “\$299 Ring” scam. The “\$299 Ring” scam involved a scheme whereby perpetrators called potential enrollees and requested bank account numbers to withdraw payment for enrollment into a nonexistent PDP.

**Data Monitoring—Neither CMS nor the MEDIC had conducted any significant data analysis for fraud detection purposes**

Data-driven fraud detection was mentioned in multiple press releases as a critical part of CMS’s fraud control strategy. However, those efforts have been slow to materialize. Electronic systems were put in place to ensure proper formatting and logical consistency in Part D claims data

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<sup>20</sup> The MEDIC complaint descriptors reflect complaints received until October 30, 2006.

<sup>21</sup> A case referral may include numerous individual complaints.

## F I N D I N G S

and controls were put in place to ensure that the extra benefits for low-income enrollees are designated appropriately. However, no significant data analysis had been conducted specifically to detect or prevent fraud and abuse.

CMS staff reported that they did not expect to begin these efforts immediately and that efforts were further delayed by a lag in data submissions. The data lag occurred because it took time for the PDPs to submit claims data properly, a consequence of a complex and quickly designed system. Additionally, CMS experienced some data problems during the early phases of implementation. One example is that some beneficiaries appeared to be incorrectly enrolled in two PDPs simultaneously, allowing drug transactions to be billed to the incorrect PDP. This problem was eventually resolved, but the process of correcting those errors did not begin until August 2006.

Another barrier to conducting data analysis was the lack of a centralized data repository. In September 2006, CMS contracted with Electronic Data Systems to be the One Program Integrity System Integrator (One PI). The One PI will warehouse Medicare data for prescription drugs, physician services, and inpatient care, among other data. This contract represents a significant step towards the use of data-driven fraud detection methods, but no actual data analysis is expected until the summer of 2007. When operational, this group will be responsible for using data analysis techniques to uncover fraud, waste, and abuse. It will also offer powerful data analysis tools and make data accessible to CMS program integrity staff and other appropriate parties via a Web-based portal.

### **Financial Audits—CMS let a contract to develop the financial audit program just before the end of FY 2006, with an expectation that the first audits will begin in January 2008**

The final reconciliation between CMS and the PDP sponsors is scheduled to begin in September 2007, following the June 30, 2007, deadline for PDPs to submit rebate information. CMS staff do not plan to begin conducting financial audits until the reconciliation is complete, which means that the earliest financial audits will likely begin in January 2008. These first audits will be designed to verify financial data for plan year 2006.

CMS is required to conduct audits on one-third of Medicare Part D organizations, including PDPs, each year. However, the one-third audit requirement does not specify that CMS audit every plan within a 3-year

period or any other timeframe. Therefore, it is conceivable that some plans would not be audited during the Part D program's initial 3-year period.

In addition, CMS staff expressed concern that funding limitations may constrain the depth and/or breadth of the audits. Although CMS took a significant step in preparation for the audits by hiring a contractor in September 2006 to develop the audit process and protocols, further and more costly steps are still needed. By September 2007, CMS expects to have a final audit process and protocol, including thresholds for audit findings and timelines for conducting audits, but still needs to hire and train additional contractors to conduct the audits. The number of staff required has not yet been determined but will likely be significant and costly. For the financial audits to proceed as planned, CMS will need to identify them as a high priority when making budget decisions.

**Monitoring PDP Sponsor Compliance—Efforts to monitor PDP sponsor compliance are in place, but compliance audits have been delayed**

Although routine account management activities and operational safeguards were in place prior to the first beneficiary enrollment period, compliance audits had not started as of the end of FY 2006. CMS staff have, however, undergone extensive preparations for conducting compliance audits. Audit protocols have been developed and many staff at CMS are reportedly trained and ready to begin the audit process. Compliance audits were scheduled to begin in the summer of 2006 but were delayed because the data system that enables CMS to schedule and track compliance audits encountered technical problems. Staff anticipated that the first audits would be conducted in early 2007.

**Oversight of PDP Efforts to Reduce Fraud and Abuse—CMS issued requirements for PDP sponsors' fraud, waste, and abuse compliance plans**

As a part of their contracts, PDP sponsors must agree to implement fraud control programs.<sup>22</sup> CMS issued guidelines to PDP sponsors before the benefit began and then updated guidance with the release of the initial chapter (issued as chapter 9) of its "Prescription Drug Benefit Manual" in April 2006. This chapter describes specific requirements for PDP sponsors' fraud, waste, and abuse compliance plans which address primarily basic infrastructure.<sup>23</sup> Specific fraud detection activities are

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<sup>22</sup> 42 CFR § 423.504(b)(vi)(H).

<sup>23</sup> Centers for Medicare & Medicaid Services, "Prescription Drug Benefit Manual," chapter 9.



recommended but are not required. CMS expected that PDPs would incorporate CMS guidance into their compliance plans by January 2007. An OIG report, “Prescription Drug Plan Sponsors’ Compliance Plans,” found that although all PDP sponsors had a plan to detect, correct, and prevent fraud, waste, and abuse in place by January 1, 2006, few PDPs addressed all of CMS’s recommendations for specific fraud and abuse detection activities.<sup>24</sup>

**Education and Guidance—Many education efforts were under way, but the slow release of two key documents raises concern**

By the end of FY 2006, CMS and the MEDIC had conducted numerous training sessions for beneficiaries, PDP sponsors, and law enforcement entities. Other educational efforts included advisory opinions, direct mailings, training, and conferences. These efforts contribute to beneficiary protection, as well as information sharing between law enforcement groups working on Medicare Part D integrity issues.

Despite these efforts, the delayed release of two critical documents raises concern. First, although CMS makes most of its Medicare Part D guidance materials available on the Internet, the agency has not yet completed the “Prescription Drug Benefit Manual.” As of the end of FY 2006, five chapters had been released in final form, including the following: 2, “Part C and D Marketing Guidelines,” 3, “PDP Enrollment and Disenrollment Guidance,” 9, “Fraud Compliance Plans,” 14, “Coordination of Benefits,” and 18, “Grievances, Coverage Determinations, and Appeals.” As a result, PDP sponsors are expected to cull the information about Medicare Part D requirements from a variety of letters and guidance documents. Second, CMS’s only Medicare Part D fraud alert issued during the first year of the program took several months to release. The alert regarded the “\$299 Ring” scam. A consumer alert was released in June 2006, but the fraud alert, which is intended to be an early alert for law enforcement entities and PDP sponsors, had not been released by the end of the fiscal year.<sup>25</sup> CMS staff explained that the delay was due to CMS’s writing, editing, and clearance process, as well as its perception that the warning was most pertinent during periods of plan marketing and open enrollment, which occurred in November 2006.

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<sup>24</sup> OEI-03-06-00100.

<sup>25</sup> The fraud alert was released in November 2006.

**In FY 2006, CMS relied largely on complaints to identify potential fraud and abuse in the Medicare Part D program; however, not all complaints were investigated timely**

With aspects of CMS’s fraud protection program not in place at the time of our review, CMS relied largely on complaints to identify potential fraud schemes and abusive practices in the first fiscal year of Medicare Part D operation. CMS staff

described complaints as an effective fraud and abuse protection tool, indicating that beneficiaries are frequently vocal about their experiences and often report suspected wrongdoing. Further, CMS staff suggested that some types of fraud are best identified by beneficiaries’ reporting directly on their experiences.

Although complaints are a valuable source of information, we noted two weaknesses in the complaint process. First, the MEDIC was battling a sizeable number of open complaint cases deemed worthy of investigation, and second, Medicare Part D fraud complaints submitted to 1-800-MEDICARE are not tracked, allowing for the possibility of missing important information from valid fraud complaints.

**Shortly after the close of FY 2006, 24 percent of the 6,132 complaints received by the MEDIC were open, most of which required further investigation**

At the time of our data collection, a single MEDIC (Delmarva Foundation), contracted to focus on enrollment and eligibility fraud in the early months of Medicare Part D operation, was responsible for tracking and investigating all fraud complaints and referring cases of merit to law enforcement. The MEDIC conducted complaint intake and triage on 6,132 complaints received during FY 2006.<sup>26</sup> The triage process is used to determine a priority level for further investigation and helps to ensure that the most serious fraud complaints are quickly identified.<sup>27</sup> A few complaints are quickly referred to an enforcement agency without ever being investigated by the MEDIC, and many others are quickly closed or referred to the PDP because it is clear that fraud is not the issue. The remaining complaints are considered “open” until the case is referred to and accepted by law enforcement or closed as a result of insufficient evidence.

<sup>26</sup> The MEDIC complaint data reflect complaints received through October 30, 2006.

<sup>27</sup> The triage process involves evaluating each complaint on five criteria: patient abuse, geographic scope of impact, monetary impact, ability to prosecute, and pattern of fraud.

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Shortly after the end of FY 2006, the MEDIC had 1,475 open complaints in various stages of investigation. These included complaints awaiting review, active investigations, and cases in the preliminary stages of referral to law enforcement agencies. Of these, almost half had been open for at least 150 days and a few had been open for 300 days or more.

The significant number of open complaints appears to be the result of an insufficient number of investigative staff. The first MEDIC contract funded only primary activities, such as complaint intake and investigation, forcing the MEDIC to reduce its original plan for the range of efforts employed and resources dedicated to fighting fraud. Although the MEDIC maintained all complaint intake activities, only three full-time and three part-time investigative staff were assigned to conduct follow-up investigations. Staff at CMS and staff at Delmarva Foundation were optimistic that, with the addition of the three regional MEDICs beginning operations in December 2006, the number of open complaints would be dramatically reduced.

### **Medicare Part D fraud and abuse complaints submitted to 1-800-MEDICARE are not logged or tracked**

Both 1-800-MEDICARE and 1-877-7SAFERX are publicized phone numbers, but 1-800-MEDICARE is designed as a resource to answer general questions and receive all types of Medicare complaints, including Medicare Part D fraud complaints. In contrast, 1-877-7SAFERX is dedicated to complaints about Medicare Part D fraud. Although the customer service representatives at 1-800-MEDICARE enter most complaints into the Complaint Tracking Module of HPMS, Medicare Part D fraud complaints are not entered. When Medicare Part D fraud is suspected, the customer service representative advises the caller to call the MEDIC at 1-877-7SAFERX. CMS does not track how many people have been advised to call the MEDIC, nor does it conduct any followup to ensure that the complainant actually called the MEDIC. To the extent that callers are not following through with calls to 1-877-7SAFERX, valid complaints could be slipping through the cracks.

**Limits to legal authority, jurisdiction, and CMS’s ability to monitor enrollees switching plans complicate CMS’s efforts to safeguard Medicare Part D PDPs**

Despite the operation of six types of safeguard activities, we identified three impediments to the effective oversight of Medicare Part D, specifically in the areas of

financial auditing, Part D marketing, and utilization management. Although these impediments are not insurmountable, they do make CMS’s Medicare Part D oversight responsibility more difficult to fulfill.

**CMS has limited ability to verify that direct and indirect remuneration are accurately reported by PDP sponsors**

After the plan year has ended, PDPs must report to CMS all outstanding financial information, including direct and indirect remuneration. Remuneration received by PDP sponsors may reduce the PDP sponsor’s cost of providing Medicare Part D drugs. Such remuneration includes manufacturer or pharmaceutical benefit manager rebates, chargebacks, discounts, goods in kind, or grants. Remuneration is deducted from PDP losses (or added to PDP profits) for the year and may have a significant impact on the final payment reconciliation between CMS and PDP sponsors, because it directly affects the amount of money that CMS will reimburse or recoup from PDPs. Underreporting remuneration could result in significant losses to the Medicare Part D program. The onus is on PDPs to accurately and completely report this information. However, CMS’s ability to check the veracity of this self-reported data is limited to financial audits, and auditors will be faced with the difficult task of identifying any remuneration that is not reported by PDPs or their subcontractors.

Additionally, CMS staff do not currently have the legal authority to go onto the premises of the pharmaceutical benefit managers to verify the flow of goods and money. Instead, CMS must rely on PDP sponsors to include sufficient requirements in their own contracts with subcontractors. Regulations require that a PDP sponsor “agrees to require all related entities, contractors, or subcontractors” to allow CMS access to documents and information for the purpose of audits.<sup>28</sup> However, if the PDP sponsors fail to include sufficient access provisions in their contracts with subcontractors, the regulations afford CMS no direct regulatory authority to independently access information.

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<sup>28</sup> 42 CFR § 423.505(i)(2).

**CMS has limited authority over insurance brokers, one of the most frequent subjects of fraud complaints**

Brokers are paid a commission to enroll eligible beneficiaries into a plan. Brokers may represent any number of PDPs and receive different commissions based on which plan is selected by the beneficiary. Dishonest brokers may inappropriately steer potential enrollees to particular plans by providing false or limited information. Some of the most egregious complaints received to date involve brokers enrolling beneficiaries without their consent. Because brokers assist in boosting enrollment numbers, plans have few incentives to rein in dishonest brokers. CMS requires that plan subcontractors, including brokers, comply with all Medicare Part D regulations, but this proves difficult to enforce with respect to brokers for several reasons. First, if CMS learns that a broker is not in compliance with Part D marketing and enrollment requirements, it cannot take direct corrective action against the broker itself. Rather, CMS would have to take enforcement actions against the PDP sponsor who contracted with the broker. Second, because brokers are regulated by State insurance commissions, the MEDIC must refer alleged broker misconduct to the appropriate State insurance commission and rely on it to take corrective actions against the broker. Third, privacy restrictions contained in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) necessitate that the MEDIC obtain consent from the enrollee before sharing case-specific information with the State insurance commission. With the cases that have been referred, the MEDIC experienced delays and sometimes difficulty getting such consent.

**Overutilization of drugs for the purpose of personal drug abuse or selling prescription drugs for profit poses a significant cost risk to Medicare Part D; however, plans are limited in their ability to monitor suspect enrollees**

Although the inappropriate costs per individual may be small, the suspected widespread nature of this type of fraud poses a significant risk to the program. The MEDIC staff is aware of approximately 60,000 persons who were identified by State Medicaid programs because they demonstrated unusual drug utilization patterns prior to their transition to Medicare Part D. Some State Medicaid programs conducted routine data checks to identify potentially inappropriate utilization by individuals, known as “overutilizers,” and took steps to control their drug access through management structures, such as prior authorizations and pharmacy restrictions. Information about specific,

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known overutilization risks in State Medicaid programs was not transferred to PDPs when the Medicare Part D benefit began. Thus, PDPs must conduct their own analysis to identify these risks. PDPs face further difficulty in developing and maintaining knowledge about potential overutilizers because most beneficiaries are able to change plans every year and Medicare/Medicaid dually eligible beneficiaries are able to change plans every month. PDPs and the MEDIC have interpreted HIPAA privacy provisions as prohibiting communication about suspected overutilizers. As such, plans must develop a new utilization profile for an enrollee each time the enrollee changes plans. HIPAA provisions allow PDPs to communicate about beneficiaries suspected of inappropriate behavior, as long as each PDP currently has or previously had a relationship with the beneficiary in question. However, there is currently no mechanism by which PDPs can identify which other PDPs have or previously had a relationship with a beneficiary.

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CMS is making progress towards fulfilling its plans for preventing and detecting fraud and abuse in PDPs; however, some activities were not fully implemented by the end of FY 2006. CMS staff report that some activities would have been premature or point to funding and data limitations as a rationale for delays. Although we recognize the short timelines and significant challenges that CMS faced in rapidly implementing the Medicare Part D program, the impact on beneficiaries as well as the large magnitude of outlays (i.e., \$47 billion in 2006) call for commensurate safeguard activities. In an effort to continue improving CMS's safeguard strategy, we recommend that CMS:

**Develop a comprehensive safeguard strategy for Medicare Part D PDPs with specific activities and target dates and ensure that all activities are progressing in a timely manner**

CMS had begun implementation activities in all safeguard areas, but CMS staff could not provide timelines for final implementation. CMS should develop a comprehensive written strategy document with specific activities and target dates and assign staff to follow up on progress. This document should serve as a management tool to coordinate different CMS groups that may have a role in safeguarding Medicare Part D PDPs and aid in identifying areas that may not be adequately protected by the safeguards that are in place. It should also be used as a prompt to notify appropriate senior staff if implementation activities fall behind schedule. Further, CMS should make Medicare Part D safeguard activities a sufficient priority in the budgeting process to support their timely and effective administration. Of foremost concern are commencement of the financial audits, sufficient MEDICs to investigate fraud complaints, and the pursuit of innovative data-driven techniques to identify potential fraud and abuse.

**Ensure that all fraud complaints receive proper attention**

As the number of MEDICs and staff assigned to investigate complaints increases, CMS should have a process in place to monitor the number of open complaints and take action if backlogs occur. Additionally, CMS should investigate options for customer service representatives to directly transfer fraud complaints received by 1-800-MEDICARE to the appropriate MEDIC.

**Address legal concerns that may impede program integrity efforts**

Three concerns in particular require attention:

*Require PDP sponsors to include standard wording regarding requirements for record retention and accessibility within subcontractor contracts.*

Verification that PDPs report all remuneration is intrinsically difficult. For this reason, it is critical for CMS to have full access to primary documentation about remuneration, including that maintained by a pharmaceutical benefit manager or other subcontractor. Further, CMS should not be limited in its ability to access critical information because only general or nonspecific requirements are included in subcontractor contracts. The standard wording should include provisions for (1) CMS accessing information directly from subcontractors; (2) timelines for both records maintenance and accessibility; (3) special circumstances, such as terminated contracts; and (4) penalties for noncompliance with records access provisions. Further, the inclusion of this language should be verified through either the financial audits or compliance audits.

*Enforce appropriate sanctions for PDPs whose brokers violate permissible marketing practices.*

The prevalence of complaints from FY 2006 indicates that improper broker marketing practices pose a significant risk for the Part D program. Although CMS may be unable to directly penalize brokers who are conducting illegal marketing practices, the PDPs have ultimate responsibility for their subcontractors.<sup>29</sup> CMS guidance requires PDPs to monitor the performance of subcontractors, including marketing practices. CMS Part D regulations also require that PDP subcontractor contracts include a provision allowing CMS or the PDP to take corrective action if either CMS or the PDP determines that the subcontractor is not performing satisfactorily.<sup>30</sup> CMS should be vigilant in its oversight of insurance brokers and ensure strong enforcement of Part D marketing standards.

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<sup>29</sup> 42 CFR § 423.505(i).

<sup>30</sup> 42 CFR § 423.505(i)(4)(ii).



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*Utilize the MEDICs as intermediaries for PDPs to share information about their beneficiaries suspected of inappropriate utilization.*

Currently, there is no way for information about extreme or unusual utilization by a particular beneficiary to be communicated between the beneficiary's prior PDP to his or her next PDP. Allowing the MEDICs to act as repositories of information about beneficiaries suspected of fraud would improve PDPs' ability to identify and monitor drug-seeking and drug-selling behavior. Further, early identification of these individuals would limit the effectiveness of a beneficiary switching plans to avoid targeted actions by the PDPs to prevent fraud. In implementing this activity, CMS should explore whether this recommendation can be addressed by revising MEDIC contracts.

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### AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments to the draft report, CMS did not indicate whether it concurred with our recommendations, but did provide comments regarding each recommendation (see Appendix B). CMS responded that many of its ongoing activities already satisfy our recommendations. It further stated that the report does not fully explain the immense workload required for CMS to develop and administer the benefit in its first year and indicated that processes and procedures have improved over time. In its technical comments, CMS reported several advances in its safeguard strategy that occurred after the end of our data collection period (FY 2006). The advances CMS reported include:

- continued progress towards commencement of the financial audits. Audits are still scheduled to begin by the end of calendar year 2007;
- successful negotiations to allow MEDICs sufficient access to PDP data so that data-driven fraud detection activities can begin;
- improvement in processing complaints timely. Specifically, CMS reported that of 5,286 complaints received by the MEDICs between December 2006 and June 2007, only 2 are older than 30 days;
- commencement of routine PDP compliance audits in February 2007;
- issuance of a self-assessment tool to assist PDPs in improving their fraud, waste, and abuse compliance plans; and

- release of four new chapters of the Prescription Drug Benefit Manual.

### **Comprehensive safeguard strategy**

Regarding our recommendation to develop a comprehensive safeguard strategy with specific activities and target dates, CMS stated that the MEDIC task orders and Umbrella Statement of Work (USOW) are CMS's comprehensive safeguard strategy for the Part D program. Additionally, CMS responded that the broader strategy for fighting fraud, waste, and abuse is the three-pronged strategy. Although OIG agrees that the task orders and USOW provide an important framework for enacting many safeguard activities, these documents are specific to the MEDIC activities and do not address the broad coordination that is needed between different groups within CMS that each have a role to play in safeguarding Medicare Part D. With regard to CMS's three-pronged strategy, the documents we reviewed lacked the details, deliverables, and timelines that would extend its use from a broad strategic concept to a useful management tool. Therefore, we continue to recommend that CMS create a comprehensive safeguard strategy that includes specific activities across the range of its existing and planned program integrity efforts and tie these activities to target dates so that implementation progress can be monitored, strengths can be identified, and delays can be addressed.

### **Fraud complaints**

Regarding our recommendation to ensure that all fraud complaints receive proper attention, CMS stated that ensuring all complaints are addressed promptly is a top priority. CMS also expressed concern that our draft report misrepresented the MEDIC's activities in responding to complaints but acknowledged early difficulties with the volume of complaints. Further, CMS stated that the three MEDICs contracted for FY 2007 would be sufficient to fully investigate and resolve fraud complaints.

Because of CMS's concern that we misrepresented the MEDIC's activities in responding to complaints, we made revisions to avoid characterizing open complaint cases as a "backlog" and to more fully describe the status of the open cases at the time of our data collection. However, the number of open cases and the time that some cases remained open suggest that the complaint process is susceptible to backlogs. Consequently, OIG continues to recommend that CMS devote

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sufficient resources to ensure that all fraud complaints receive proper attention, including implementing a system to monitor the complaint caseload for potential backlogs.

CMS also stated that it will explore the feasibility of transferring Part D fraud calls from 1-800-MEDICARE directly to the MEDIC hotline and that, until a decision is made, 1-800-MEDICARE customer service representatives will remain responsible for making determinations as to whether calls should be sent to MEDICs. We clarify that the intent of this recommendation is to ensure that once a fraud complaint is identified, complainants should be directly connected to the MEDIC, rather than being advised to call the MEDIC hotline. We expect that customer service representatives will continue to be responsible for identifying which calls should be directly connected to the MEDIC.

### **Address legal concerns**

Regarding our recommendation to pursue legal authority to obtain records directly from subcontractors and to explicitly require subcontractors to retain their documents, CMS stated that it currently has authority to obtain records from subcontractors and that requirements for record retention already exist. OIG interprets the existing authority as being dependent on the inclusion of sufficient contractual language by PDP sponsors within their subcontractor contracts. We modified this recommendation to more specifically address this underlying concern.

Regarding our recommendation to enforce appropriate sanctions for PDPs whose brokers violate permissible marketing practices, CMS described its authority and a range of potential sanctions it is able to impose in the event of noncompliance with marketing guidelines.

Regarding our recommendation to utilize the MEDICs as intermediaries for PDPs to share information with each other about suspected fraud, CMS stated that it will evaluate the possibility and potential implications of having the MEDICs serve as the intermediaries for PDP data.

### **Request for final comments**

We ask that, in its final management decision, CMS indicate whether it concurs with our recommendations and what steps, if any, it will take to implement them.



## **Medicare Part D Benefits and Operation**

Medicare Part D benefits are provided by private insurers, either in the form of a stand-alone PDP or as part of a comprehensive Medicare managed care plan, known as a MA-PD. PDP plans provide Medicare beneficiaries access to prescription drugs for low monthly premiums and copayments. The MA-PD plans include hospital and physician insurance, as well as the prescription drug benefits. For 2006, there were 1,429 PDPs and 1,314 MA-PDs.

Medicare Part D plans provide coverage that is at least actuarially equivalent to a defined standard benefit. The defined standard benefit in 2006 provided coverage in four progressive phases: (1) a \$250 deductible; (2) beneficiary coinsurance of 25 percent of drug costs between \$250 and \$2,250; (3) coverage gap with the beneficiary responsible for all drug costs between \$2,250 and \$5,100; and (4) catastrophic coverage with a beneficiary coinsurance of 5 percent for all drug costs over \$5,100. Most drug plans offered in 2006 opted for an alternative benefit structure, but the defined standard benefit still serves as the baseline. Although beneficiary-paid premiums and other cost sharing cover approximately 25 percent of the program's expected cost, the remaining 75 percent is drawn from the Medicare Trust Fund.

## **Medicare Part D Program Operations**

Managing the Medicare Part D program requires many coordinated activities. For each year, prospective sponsors must submit an application demonstrating that all qualifications will be met, including an acceptable formulary. CMS staff review the applications and formularies to determine an intent to comply with program requirements. Accepted applicants may then submit bids, which include the benefit designs and attestations that the benefit is actuarially equivalent to the defined standard benefit; the expected costs of the program; and any cost utilization controls that will be employed. Once the bid is deemed acceptable, a contract is let with the plan sponsor and the private organization agrees to abide by all Medicare Part D regulations.

Plans may begin marketing activities the October prior to the beginning of the plan year. All marketing materials must either use standardized language that is on file with CMS or have CMS review the materials for accuracy and appropriateness. Open enrollment begins on November 15, which allows enrollees to select a plan or change their plan designations. Enrollees may evaluate plan options by their use of


premiums, deductibles, and copays; the drugs allowed through the formularies; restrictions that may be placed on drug utilization; and the benefit designs to determine which plan best accommodates their needs. Several resources are available to assist beneficiaries in making their selections, including the Web-based plan finder and 1-800-MEDICARE staff. Some enrollees with low income qualify for additional financial assistance to cover the costs of premiums, deductibles, and copays. Enrollees that are dually eligible for Medicare and Medicaid will be automatically assigned to plans if they do not select plans themselves.

Once the plan year begins, enrollees are entitled to the prescription drug benefits offered by their selected plans. The plans record each pharmacy transaction and report summary information about the transaction to CMS. The information reported to CMS is called the Prescription Drug Event and is used for a year-end reconciliation. The plans, however, hold the primary responsibility for tracking each beneficiary's total drug costs and out-of-pocket expenses. Beneficiary drug costs and out-of-pocket expenses (formally called true-out-of-pocket, or TrOOP) determine when the beneficiary enters particular phases of the benefit. Specifically, total drug costs determine when a beneficiary enters the coverage gap and TrOOP determines when the catastrophic benefit begins.

CMS pays plans prospectively; however, certain payments are reconciled after the end of the plan year. CMS's payments to plans include: (1) a risk-adjusted prospective payment for each beneficiary enrolled, each month; (2) a subsidy to account for the lower premiums, deductibles, and copayments offered to qualifying low-income enrollees; (3) reinsurance for a portion of drug costs incurred by plans during the catastrophic coverage phase; and (4) a payment adjustment (positive or negative) for a predetermined risk-sharing agreement. The reconciliation process does not begin until plans have fully disclosed their direct and indirect remuneration, e.g., rebates, due approximately 6 months after the end of the plan year. Consequently, payments are not fully adjudicated until several months after the plan year, at a minimum.

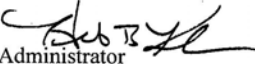
A P P E N D I X B

Agency Comments

	DEPARTMENT OF HEALTH & HUMAN SERVICES	Centers for Medicare & Medicaid Services
	Office of the Administrator Washington, DC 20201	

**DATE:** AUG - 9 2007

**TO:** Daniel R. Levinson  
Inspector General

**FROM:** Herb B. Kuhn   
Acting Deputy Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: "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)

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GENERAL

Thank you for the opportunity to review and comment on the OIG draft inspection report to determine the extent to which the Centers for Medicare & Medicaid Services (CMS) implemented safeguards during fiscal year (FY) 2006 to prevent and detect fraud and abuse in Medicare prescription drug plans (PDPs). It is important to note that this report covers the inaugural year of the Part D benefit. As a consequence, CMS asserts that our efforts to implement safeguards for the Part D benefit be analyzed in two 6-month parts--the start up of the benefit and the administration of the benefit. In previous discussions with the OIG, CMS has asserted that the report does not fully explain the immense workload that had to be successfully completed in an extremely short period of time in order to initiate the benefit on January 1, 2006. By analyzing the CMS efforts in this way, the OIG would provide a more realistic illustration of how all processes and procedures improved as the benefit was administered.

**OIG Recommendation**  
Develop a comprehensive safeguard strategy for Medicare Part D PDPs with specific activities and target dates and ensure that all activities are progressing in a timely manner.

**CMS Response**  
The individual task orders and the Umbrella Scope of Work (USOW) are CMS' comprehensive safeguard strategy for the Part D program. CMS' strategy for fighting fraud, waste, and abuse in Part D is a 3-pronged approach--investigating incoming complaints, performing data analysis, and working with law enforcement. CMS has augmented its three-pronged approach by tripling the number of staff working for the Medicare Drug Integrity Contractors (MEDICs), as well as broadening the scope of activities that they perform.

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Under the USOW the MEDICs are contractually required to produce certain deliverables, which include, but are not limited to:

- Monthly status reports;
- Monthly cost reports;
- A public relations plan;
- A monthly summary of law enforcement referrals; and
- Quarterly vulnerabilities reports.

Each MEDIC is assigned a Government Task Lead (GTL) to ensure accessibility to CMS, track progress on deliverables, and provide technical guidance. The GTLs also coordinate the activities of the MEDICs with other CMS components and are responsible for alerting management of any issues with the MEDICs. The GTLs have weekly MEDIC meetings to monitor MEDIC activities for timeliness and congruency. The MEDIC meeting provides a forum to facilitate discussions regarding emerging trends with respect to fraud, waste, and abuse in the Medicare Part D program. It also provides an opportunity for CMS and the MEDICs to discuss Part D program operational issues and give status updates on current projects or pending reports that are underway.

The CMS believes that the three current MEDICs are sufficient to fully investigate and resolve fraud complaints. In addition, CMS has sufficient funding to support the MEDICs through the end of this contract year. CMS anticipates securing funding for the MEDICs to allow them to conduct more proactive initiatives to actually prevent fraud from occurring, rather than primarily reacting to complaints. The financial audits have not begun because the Part D plans are just now submitting their final Direct and Indirect Remuneration and Prescription Drug Event data to CMS. Once all the data have been received by CMS, there must be a reconciliation completed before any of the audit work can begin. We anticipate that financial audits will begin by the end of this calendar year. Our top priority is to increase the MEDICs' access to Part D data. Additional funding will support the MEDICs' access to data sources and allow the MEDICs to provide additional analysis and thus sustain fraud, waste, and abuse prevention activities by linking records across the Medicare and Medicaid programs.

In response to the comment that "CMS staff was sometimes vague about timelines for final implementation," it should be noted that interviews for this report were conducted around the time of contract award for the three regional MEDICs. Due to the impending transition and the proprietary nature of the USOW and task orders for the MEDICs, we were unable to discuss the specifics of the activities of the MEDICs at the time the OIG developed this report.

**OIG Recommendation**

Ensure that all fraud complaints receive proper attention.

**CMS Response**

The CMS has made it a top priority to ensure that all complaints of the Part D program are addressed promptly. Given that the first year of the benefit's implementation was challenging on many fronts, CMS is concerned that the OIG is misrepresenting the

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MEDICs' activities in responding to complaints. With over 500 new Part D Sponsors offering a brand new Medicare benefit, virtually everyone impacted by the Part D benefit required CMS assistance in understanding not only how to administer the benefit but also how to effectively educate every beneficiary on the benefit. There was no way for CMS to gauge the amount of questions and confusion about the benefit ahead of time. As a result, the MEDICs spent a great deal of time sorting through whether concerns raised were legitimate complaints or misunderstandings of the benefit.

The CMS acknowledges that in the first few months of 2006 the only existing MEDIC was not adequately prepared for the volume of complaints. Since the beginning of the benefit, CMS has allocated more resources to the MEDICs to ensure that complaints are investigated and resolved in a timely manner. With the addition of these resources, the MEDICs have not had a complaint backlog since that initial period at the beginning of the benefit.

The CMS will explore the feasibility of transferring all Part D fraud calls from 1-800-MEDICARE directly to the appropriate MEDIC. Until a decision is made on this, 1-800-MEDICARE Customer Service Representatives will remain responsible for making a determination as to whether a call should be sent to a MEDIC.

**OIG Recommendation**

Pursue legal authority to obtain records directly from PDP sponsors subcontractors and explicitly require that subcontractors retain Medicare Part D documents for an appropriate and specific timeframe.

**CMS Response**

The CMS already has the legal authority to obtain records directly from PDP sponsors and subcontractors and requires that subcontractors retain Part D documents for an appropriate and specific timeframe. CMS already has the authority to view the failure by a first tier, downstream, or related entity to provide information requested by CMS or the Department of Health and Human Services (HHS) as a contract violation by the Part D plan sponsor.

With respect to the timeframe, section 423.505(i)(2) of the regulations requires that a Part D sponsor maintain books, records, documents, and other evidence of accounting for 10 years. CMS also advised Part D sponsors of this requirement in the 2007 Medicare Prescription Drug Benefit application. The subcontractors (first tier, downstream, and related entities) of Part D sponsors are also bound by this requirement. The regulations at section 423.505(e)(2) and (e)(4) give HHS, the Comptroller General, or their designees the right to inspect, evaluate, and audit the books and records of subcontractors and state that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later.

**OIG Recommendation**

Enforce appropriate sanctions for PDPs whose brokers violate permissible marketing practices.



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**CMS Response**

The CMS treats agents and brokers as subcontractors to PDP sponsors. As such, CMS holds sponsors responsible for the conduct of any agents and brokers they may hire to sell Part D products. Currently, when CMS determines that agents and brokers are not in compliance with Part D marketing and enrollment requirements (largely through complaints from beneficiaries and State officials), CMS takes enforcement actions against the PDP sponsor whose products the agents are selling. Depending on the severity and frequency of the violations, CMS may take a range of compliance actions, from issuing formal warning notices to the sponsor, up to the imposition of intermediate sanctions (e.g., suspension of marketing and enrollment activities) and PDP sponsor contract termination.

**OIG Recommendation**

Utilize the MEDICs as intermediaries for PDPs to share information about their beneficiaries suspected of inappropriate utilization.

**CMS Response**

We are currently evaluating the possibility and the potential implications of having the MEDICs serve as the intermediaries for PDP data.

The CMS thanks the OIG for their efforts on this report. We look forward to working together with you in the future as we continue to prevent fraud, waste, and abuse in the Medicare Part D program.



## A C K N O W L E D G M E N T S

This report was prepared under the direction of Kevin K. Golladay, Regional Inspector General for Evaluation and Inspections and A. Blaine Collins, Deputy Regional Inspector General for Evaluation and Inspections in the Dallas regional office.

Amy Ashcraft served as the team leader for this study, and Tom Browning served as the lead analyst. Central office staff who contributed include Linda Abbott.