

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PRESCRIPTION DRUG PLAN
SPONSORS' COMPLIANCE PLANS**



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OBJECTIVES

(1) To determine whether prescription drug plan sponsors have developed compliance plans as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and

(2) To determine whether prescription drug plan (PDP) sponsors' compliance plans, as of January 2006, addressed all of the requirements and selected recommendations regarding the eight compliance elements presented in Federal regulations.

BACKGROUND

As of January 1, 2006, all 43 million Medicare beneficiaries became eligible to enroll in the new Part D prescription drug benefit established through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173). Part D coverage is provided through private drug plans offered by plan sponsors. These plans include mainly stand-alone PDPs and Medicare Advantage plans that offer integrated coverage for both prescription drugs and other health care. For this report, we limited our review to stand-alone PDP sponsors' compliance plans.

Pursuant to 42 CFR § 423.504(b)(4)(vi), PDP sponsors approved to provide Part D benefits in 2006 are required to have compliance plans in place. These compliance plans must address eight elements, which are listed on page 2 of this report. The Office of Inspector General (OIG) has consistently recommended in its Compliance Program Guidances that compliance programs be implemented in a manner that addresses organizations' specific operations and risk areas. A successful compliance program helps sponsors protect the integrity of Medicare funds and may also improve Part D plans' efficiency and effectiveness.

Beginning in November 2005, we requested copies of PDP sponsors' compliance plans to determine whether they addressed the eight required elements. We asked sponsors to provide all documents that made up their compliance plans. By January 2006, we received compliance plans covering all 79 stand-alone PDP contracts.

To determine whether PDP sponsors' compliance plans addressed the eight elements in Federal regulations (42 CFR § 423.504(b)(4)(vi)), we reviewed each plan using information in the Centers for Medicare & Medicaid Services' (CMS) summary document, issued in June 2005,

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entitled “Review of Sponsors’ Fraud, Waste, and Abuse Responsibilities;” and the fraud, waste, and abuse chapter of CMS’s “Prescription Drug Benefit Manual,” issued in April 2006.

In the “Prescription Drug Benefit Manual” chapter, CMS outlines requirements that sponsors’ compliance plans must address to ensure that the eight elements established by regulation are met. While the manual chapter outlines CMS’s current expectations for sponsors’ compliance plans, the June 2005 summary document was the only CMS guidance available to PDP sponsors when we began our review. Therefore, we reviewed plans for 17 of the requirements included in the initial summary document. These 17 requirements were later included in CMS’s manual chapter as well.

The 17 requirements we reviewed were associated with the 8 regulatory compliance plan elements. For the eighth element, which involves a comprehensive fraud and abuse plan, the summary document and manual chapter both include a requirement that PDP sponsors develop fraud and abuse plans. Neither the summary document nor the manual chapter provides any additional requirements regarding the development of fraud and abuse plans. However, the manual chapter does provide recommendations to sponsors concerning fraud and abuse plans. Comprehensive fraud and abuse plans are important to maintaining the integrity of the Part D benefit. Therefore, we also selected for review 11 recommendations from the manual chapter that are specific to the detection, correction, and prevention of fraud, waste, and abuse. This review enabled us to determine how sponsors’ compliance plans addressed the development of fraud and abuse programs in the early stages of the Part D benefit.

We reviewed compliance plans to determine whether they addressed the 17 requirements and 11 recommendations. Our initial reviews revealed that some compliance plans included language that merely restated the text of the requirements and recommendations. Therefore, for six requirements and six recommendations we assessed whether each plan provided specifics on how the sponsor intended to implement the requirement or recommendation. When a plan included these specifics, we determined that it provided detailed information about the requirement or recommendation.

FINDINGS

All PDP sponsors had compliance plans, yet 72 of the 79 plans did not address all CMS requirements regarding the eight compliance plan elements.

As of January 2006, all sponsors had compliance plans covering the 79 PDP contracts. Federal regulations outline eight elements PDP sponsors must include in their compliance plans, and CMS guidance documents specify that plans must address 17 requirements regarding the eight elements. Seventy-two of seventy-nine compliance plans did not address all 17 requirements. Sponsors' compliance plans addressed a median of 13 of these requirements. For six of the eight elements, all or almost all plans addressed every requirement. However, many sponsors' compliance plans did not address requirements relating to two elements: designation of a compliance officer and compliance committee, and procedures for internal monitoring and auditing. These elements are essential to the implementation of a successful compliance program. Compliance officers are focal points for organizations' compliance activities and compliance committees assist in compliance program implementation. Ongoing monitoring and auditing is a critical process that enables organizations to identify and respond to compliance issues timely and to review whether compliance plan elements are functioning appropriately.

Over half of the compliance plans that addressed six requirements involving compliance processes or programs did not contain detailed information about these requirements. Details about the implementation of various compliance plan requirements are essential for ensuring that a compliance plan is actually functioning within an organization. The six requirements are: compliance training programs, processes for reporting compliance violations, internal monitoring and auditing procedures, contractor monitoring and auditing procedures, procedures for responding to compliance violations, and procedures for implementing corrective actions. These requirements correspond to four of the eight compliance plan elements outlined in Federal regulations.

While all compliance plans addressed the fraud and abuse element in some way, only 15 of 79 plans addressed all 11 recommendations that we reviewed regarding fraud detection, correction, and prevention.

While sponsors' compliance plans are required to include comprehensive plans to detect, prevent, and correct fraud, waste, and abuse, CMS's manual chapter includes only recommendations regarding

the design of these antifraud plans. All compliance plans addressed at least two of these recommendations, yet only 15 of 79 plans (19 percent) addressed all 11 CMS recommendations that we included in our review. At the median, plans addressed 7 of the 11 recommendations. Plans most often did not address CMS recommendations relating to sponsors' fraud detection procedures, fraud awareness training, and efforts to coordinate and cooperate with CMS and law enforcement entities regarding potential fraud. Effective compliance plans describe sponsors' plans for monitoring organizational activities for potential fraud; educating employees and enrollees about fraud, waste, and abuse; and coordinating with Government authorities regarding fraud.

We determined whether compliance plans included detailed information for six recommendations regarding the establishment of fraud detection, correction, and prevention procedures. Even among compliance plans that addressed these recommendations, over 40 percent did not include detailed information.

RECOMMENDATION

This report provides results of our early review of PDP sponsors' compliance plans. When implemented successfully, a compliance plan that includes a comprehensive fraud, waste, and abuse program helps sponsors protect the integrity of Medicare funds and may also improve the operating efficiency and effectiveness of sponsors' PDPs.

We found that all PDP sponsors have compliance plans. However, these plans have not fully addressed all of the requirements that CMS specified in its guidance documents for the eight required compliance plan elements. In addition, our findings suggest that certain PDP sponsors' compliance plans contain only the broad outlines of a fraud and abuse plan. These compliance plans do not include descriptions of specific processes to implement and monitor a fraud and abuse plan. Effective compliance plans should include detailed and specific policies and procedures for how plan elements will be implemented.

CMS has not specifically audited PDP sponsors' compliance plans or fraud, waste, and abuse programs to determine whether sponsors have addressed the eight elements established by regulation.

Therefore, CMS should:

Ensure that PDP sponsors' compliance plans address all requirements.

The manual chapter issued by CMS in April 2006 includes both required and recommended provisions regarding compliance plan elements. CMS should ensure that sponsors' compliance plans address all requirements presented in its manual chapter regarding the eight elements set forth in regulation. CMS should also encourage sponsors to provide sufficient detail in their compliance plans to clearly demonstrate how sponsors are actually implementing the compliance plan requirements.

AGENCY COMMENTS

CMS agreed that effective compliance plans are an important tool for monitoring fraud, waste, and abuse in PDP sponsors' Part D plans and concurred with OIG's recommendation. CMS stated that routine audits beginning in 2007 will review the required compliance plan elements and that sponsors will be accountable for meeting all requirements.

CMS provided additional comments and context on some issues in the report. CMS suggested changes to language in the report concerning CMS oversight of sponsors' compliance plans and sponsors' voluntary reporting of possible fraud or misconduct to Government authorities. CMS also noted that it would not be possible for compliance plans to have addressed requirements included in the manual chapter in April 2006 because OIG reviewed compliance plans before the final manual chapter was published.

The full text of the comments are presented in Appendix C.

OFFICE OF INSPECTOR GENERAL RESPONSE

CMS's planned audits, as described, address our recommendation. We have revised language in the body of the report and in the recommendation section to address CMS's concerns about oversight of sponsors' compliance plans and sponsors' reporting procedures.

We also revised wording in the report to clarify that the 17 requirements included in our review were contained in the summary document issued to PDP sponsors in June 2005. These requirements were later included in CMS's manual chapter as well. Therefore, the PDP sponsors' compliance plans should have addressed the 17 requirements at the time of our review.

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OBJECTIVES

- (1) To determine whether prescription drug plan sponsors have developed compliance plans as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and
- (2) To determine whether prescription drug plan (PDP) sponsors' compliance plans, as of January 2006, addressed all of the requirements and selected recommendations regarding the eight compliance elements presented in Federal regulations.

BACKGROUND

Medicare Coverage of Prescription Drugs

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) established Medicare Part D to provide outpatient prescription drug benefits under the Medicare program. As of January 1, 2006, all 43 million¹ Medicare beneficiaries became eligible to enroll in the new Part D prescription drug benefit. It is estimated that the Part D benefit will cost \$31 billion in 2006 and \$768 billion over 10 years.²

Part D coverage is provided through private drug plans offered by plan sponsors. These plans include mainly stand-alone PDPs and Medicare Advantage plans that offer integrated coverage both for prescription drugs and for other health care.³ For this report, we limited our review to stand-alone PDP sponsors' compliance plans. As of June 2006, more than 22 million Medicare beneficiaries were enrolled in a Part D drug plan; 16.4 million of these beneficiaries were enrolled in stand-alone PDPs.⁴

Prescription Drug Plan Sponsors' Compliance Plans

Entities that sought to become PDP sponsors were required to complete an application and bidding process that began in January 2005.⁵ The Centers for Medicare & Medicaid Services (CMS) awarded contracts to successful applicants in September 2005. PDP sponsors are required to implement compliance plans that include comprehensive plans to detect, correct, and prevent fraud, waste, and abuse.⁶ A successful compliance program helps sponsors protect the integrity of Medicare funds and may also improve Part D plans' efficiency and effectiveness.

To qualify to become a PDP sponsor, applicants were required to attest in Section 3.12 of the PDP sponsor application that their compliance plans addressed the eight elements required in Federal regulations.

As listed in 42 CFR § 423.504(b)(4)(vi), the eight elements PDP sponsors' compliance plans must contain are:

- (1) Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.
- (2) The designation of a compliance officer and compliance committee accountable to senior management.
- (3) Effective training and education between the compliance officer and organization employees, contractors, agents, and directors.
- (4) Effective lines of communication between the compliance officer and the organization's employees, contractors, agents, directors and members of the compliance committee.
- (5) Enforcement of standards through well-publicized disciplinary guidelines.
- (6) Procedures for effective internal monitoring and auditing.
- (7) Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's contract as a Part D plan sponsor.
- (8) A comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse. This fraud and abuse plan should include procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to the appropriate government authority.⁷

In addition to attesting that their compliance plans addressed these elements, applicants were asked to provide narrative responses describing the sections of their compliance plans related to fraud, waste, and abuse as they would apply to the operation of the Medicare Part D benefit.

According to the PDP sponsor application instructions, CMS expected compliance plans containing these elements to be in place by September 15, 2005.⁸

Compliance Plan Guidance for Prescription Drug Plan Sponsors

In June 2005, CMS issued an eight-page summary document, "Review of Sponsors' Fraud, Waste, and Abuse Responsibilities," containing compliance plan guidance for applicants to use during the bidding process. On February 8, 2006, CMS issued more detailed guidance in the form of a draft chapter for its "Prescription Drug Benefit Manual" and solicited PDP sponsors' comments. In April 2006, CMS finalized the chapter of the

“Prescription Drug Benefit Manual” outlining the requirements and recommendations for compliance plans. CMS specified multiple requirements for four of the eight compliance plan elements. For each of the remaining four elements, CMS specified only one requirement, which is essentially the same as the element.

The manual chapter CMS developed for PDP sponsors is similar to Compliance Program Guidances the Office of Inspector General (OIG) has been issuing since 1998 for health care entities such as hospitals, home health agencies, durable medical equipment companies, and managed care organizations. The OIG Compliance Program Guidances contain elements that are the same as the first seven compliance plan elements specified in the Part D regulations.⁹ OIG has reiterated in each of its Compliance Program Guidances that all of these compliance plan elements are essential to developing an effective compliance program that reduces an organization’s vulnerability to fraud, waste, and abuse.

Antifraud, Waste, and Abuse Plans (Eighth Element)

PDP sponsors’ compliance plans must address eight elements. For the eighth element, which involves a comprehensive fraud and abuse plan, CMS’s manual chapter requires PDP sponsors to develop fraud and abuse plans but does not provide any other specific requirements. However, the manual chapter does provide recommendations to sponsors concerning fraud and abuse plans. The manual chapter explains that these recommendations provide sponsors with a road map to develop and implement effective fraud, waste, and abuse programs to protect Part D plans and the Medicare Trust Fund. The manual chapter also states that sponsors may either create a separate fraud, waste, and abuse program or integrate fraud, waste, and abuse provisions into the other seven elements of their compliance plans.

Oversight of Prescription Drug Plan Sponsors’ Compliance Activities

CMS’s “Part D Oversight Strategy for Contractors/Industry” specifies that new Medicare Drug Integrity Contractors (MEDIC) will be responsible for many Part D oversight activities. MEDICs’ responsibilities include analyzing claims and other data, investigating potential fraud and abuse, referring potential fraud cases to appropriate law enforcement agencies or CMS, conducting program integrity audits, and reviewing the fraud and abuse components of PDP sponsors’ compliance plans. CMS has already selected several companies as MEDICs, but has not yet assigned any task orders to these companies to review PDP sponsors’ compliance efforts or fraud, waste, and abuse programs. As of August 2006, only one MEDIC was operating under an approved task order. This MEDIC’s efforts have

focused on processing complaints regarding Part D fraud, waste, and abuse, particularly in the areas of enrollment and marketing.

METHODOLOGY

Compliance Plan Request

To determine whether PDP sponsors developed compliance plans as required by Federal regulations, we requested copies of compliance plans for the 79 stand-alone PDP contracts with CMS. For each contract, we mailed a letter to the PDP sponsor asking it to provide all documents that made up its compliance plan.

We collected compliance plans between November 2005 and January 2006. We received 60 compliance plans covering all 79 contracts. Several PDP sponsors operate multiple prescription drug plans across the country, but each of these sponsors has just one compliance plan in place to cover all of its PDPs. In our analysis, we counted a compliance plan that covered multiple PDP contracts once for every contract it covered. Therefore, the total number of compliance plans referred to in this report is 79.

Compliance Plan Review

To determine whether PDP sponsors' compliance plans addressed CMS's requirements and recommendations regarding the eight elements, we developed a detailed checklist and used it to review each compliance plan. The checklist contained eight sections corresponding to the eight required compliance plan elements. We based the checklist on statements included in CMS's summary document issued June 2005, entitled "Review of Sponsors' Fraud, Waste, and Abuse Responsibilities" and on the fraud, waste, and abuse chapter of CMS's "Prescription Drug Benefit Manual," issued in April 2006.

For nearly all checklist items, we adopted a very broad approach to determining whether the text of a plan addressed a compliance plan requirement or recommendation. Two requirements regarding the second element were exceptions to this approach. These requirements state that sponsors must designate a compliance officer and compliance committee. We reviewed plans for specific evidence that a sponsor had designated a compliance officer and compliance committee to determine if the compliance plan had addressed these requirements.

We did not attempt to assess the quality of the plans, nor the extent to which the plans had been implemented as part of PDP sponsors' operations. Some sponsors provided us with the compliance plan section of

the completed PDP application that they submitted to CMS for approval in 2005. We did not include these documents in our review.

Requirements for Eight Compliance Plan Elements

In the manual chapter, CMS outlines requirements that sponsors’ compliance plans must address to ensure that the eight elements established by regulation are met. CMS’s manual chapter distinguishes between statutory or regulatory program requirements that must be included in sponsors’ compliance plans and recommendations that CMS suggests sponsors address in their plans.

While the manual chapter issued in April 2006 outlines CMS’s current expectations for sponsors’ compliance plans, the June 2005 summary document was the only CMS guidance available to PDP sponsors when we began our review. Therefore, we reviewed plans for 17 of the requirements included in the initial summary document. These 17 requirements were later included in CMS’s manual chapter as well.

We used the 17 requirements to determine whether sponsors’ compliance plans addressed the eight compliance plan elements. For four elements (1, 3, 5, and 8), the CMS guidance specifies only one requirement, which is essentially the same as the element. Compliance plan elements and the requirements related to each element are presented in Table 1 below.

Table 1. Eight Compliance Plan Elements and Seventeen Related CMS Requirements

Element 1: Written policies, procedures, and standards of conduct articulating the organization’s commitment to comply with all applicable Federal and State standards*
1. Sponsor has written policies, procedures, and standards of conduct articulating the organization’s commitment to comply with all applicable Federal and State standards.
Element 2: The designation of a compliance officer and compliance committee accountable to senior management
2. Sponsor has a compliance officer in place.
3. Sponsor has a compliance committee in place.
4. Sponsor has established a compliance committee that is overseen by the compliance officer, advises the compliance officer, and assists in the implementation of the compliance program.
5. Compliance officer is responsible for developing, operating, and monitoring the fraud, waste, and abuse program.
Element 3: Effective training and education between the compliance officer and organization employees, contractors, agents, and directors*
6. Sponsor has a training and education program in place.

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Element 4: Effective lines of communication between the compliance officer and the organization’s employees, contractors, agents, directors, and members of the compliance committee
7. Sponsor has established lines of communication to provide organization-wide information about how to report compliance concerns and suspected or actual misconduct.
8. Sponsor has mechanisms in place for capturing concerns and risks, such as hotlines, suggestion boxes, or employee exit interviews.
Element 5: Enforcement of standards through well-publicized disciplinary guidelines*
9. Sponsor enforces standards through disciplinary guidelines.
Element 6: Procedures for effective internal monitoring and auditing
10. Sponsor has an internal monitoring and auditing program.
11. Sponsor has a plan in place to monitor and audit contractors’ responsibilities and activities.
12. When requested, sponsor is prepared to allow CMS to audit its financial records.
13. Sponsor allows access to any auditor acting on behalf of the Federal Government or CMS to conduct an onsite audit.
14. Sponsor’s contractors provide records to CMS or its designee.
Element 7: Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization’s contract as a Part D plan sponsor
15. Sponsor has procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives.
16. Sponsor conducts appropriate corrective actions in response to potential violations.
Element 8: A comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse*
17. Sponsor has a comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse.

*For this element, CMS guidance specifies only one requirement which is essentially the same as the element.

Our initial reviews revealed that some compliance plans included language that merely restated the text of the requirements. We therefore selected six CMS requirements (numbers 6, 7, 10, 11, 15, and 16 in Table 1 above) for which we assessed whether each plan provided specifics on how the sponsor intended to implement the requirements. When a plan included these specifics, we determined that the plan provided detailed information about the requirements.

Recommendations for Eighth Compliance Plan Element

For the eighth element, regarding a comprehensive fraud and abuse plan, the summary document and manual chapter both include a requirement that PDP sponsors develop fraud and abuse plans. Neither the summary document nor the manual chapter provides any other specific requirements regarding the development of such plans; however, the manual chapter does provide recommendations to sponsors concerning fraud and abuse plans. Comprehensive fraud and abuse plans are important to maintaining the integrity of the Part D benefit. Therefore, we selected for

review 11 recommendations from the manual chapter that are specific to the detection, correction, and prevention of fraud, waste, and abuse. This review enabled us to determine how sponsors’ compliance plans addressed the development of fraud and abuse programs in the early stages of the Part D benefit.

We reviewed sponsors’ compliance plans to determine whether they addressed the 11 recommendations. Compliance plans that addressed at least one of these CMS recommendations were considered to have addressed the requirement for the eighth element. The 11 selected recommendations related to the eighth element are presented in Table 2.

We selected six recommendations (numbers 1, 2, 3, 7, 8, and 10 in Table 2) for which we assessed whether each plan provided specifics on how the sponsor intended to implement the recommendations. When a plan included these specifics, we determined that the plan provided detailed information about the recommendations.

Table 2. Eleven CMS Recommendations Regarding Sponsors’ Antifraud Plans

Element 8: A comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse
1. Sponsor has procedures for the identification of fraud, waste, and abuse in its network.
2. Sponsor has a process to identify overpayments at any level within its network and to properly repay such overpayments in accordance with CMS policy.
3. Sponsor has policies and procedures for coordinating and cooperating with MEDICs, CMS, and law enforcement, including policies that fully cooperate with any audits conducted by the abovementioned entities or their designees.
4. Sponsor’s compliance officer’s duties include responding to reports of potential and actual instances of Part D fraud, waste, or abuse, including the coordination of internal investigations and the development of appropriate corrective or disciplinary actions.
5. Sponsor’s compliance officer’s duties include maintaining documentation for each report of potential fraud, waste, or abuse received through any of the reporting methods (i.e. hotline, mail, in-person) which summarizes the initial report of noncompliance, the investigation, the results of the investigation, and all corrective and/or disciplinary action(s) taken as a result of the investigation.
6. Sponsor’s compliance training addresses pertinent laws related to fraud and abuse.
7. Sponsor has various methods to educate enrollees on prescription drug fraud, waste, and abuse.
8. Sponsor has procedures for internal monitoring and auditing to test and confirm compliance with the Part D benefit regulations, subregulatory guidance, contractual agreements, and all applicable State and Federal laws, as well as internal policies and procedures to protect against potential fraud, waste, or abuse.
9. Sponsor receives and reviews at least one of the following data reports: payment reports, drug utilization reports, prescribing patterns by physician reports, geographic ZIP reports.
10. Sponsor conducts data analysis that includes the comparison of claim information against other data (e.g., provider, drug provided, diagnoses, or beneficiaries) to identify potential errors and/or potential fraud.
11. Sponsor has procedures in place to voluntarily self-report potential fraud or misconduct to Government authorities such as OIG (through OIG’s Provider Self-Disclosure Protocol) or the Department of Justice.

I N T R O D U C T I O N

Standards

This inspection was conducted in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

► FINDINGS

All PDP sponsors had compliance plans, yet 72 of the 79 plans did not address all CMS requirements regarding the eight compliance plan elements

As of January 2006, all sponsors had compliance plans covering the 79 PDPs. Some sponsors submitted compliance documents that had been prepared by their pharmacy benefit managers or parent organizations.

Compliance plans ranged in length from a nine-page document to two large binders full of compliance information. Some compliance plans were a collection of policy and procedure documents, while other plans were individual documents divided into chapters for different compliance issues.

Federal regulations concerning PDPs outline eight elements that sponsors must include in their compliance plans.¹⁰ CMS's guidance documents specify 17 requirements relating to the eight compliance plan elements. Sponsors' compliance plans addressed between 6 and 17 of these requirements. Seventy-two of the seventy-nine compliance plans did not address all 17 requirements. Sponsors' plans addressed a median of 13 requirements. Table 1 in the Appendix provides information on the number of plans that did not address each of the 17 requirements.

All or almost all of the compliance plans addressed every requirement relating to six of the eight elements. Many sponsors' compliance plans did not address requirements relating to two elements: designation of a compliance officer and compliance committee, and procedures for internal monitoring and auditing.

Compliance officer and compliance committee. Twenty-one compliance plans did not address all requirements regarding the compliance officer and compliance committee element. Four of these twenty-one plans did not address the compliance officer and compliance committee element in any way.

Twelve compliance plans did not indicate that sponsors designated a compliance officer. Eleven compliance plans did not indicate that sponsors designated a compliance committee. Federal regulations state that all PDP sponsors must have a compliance officer and compliance committee in place.¹¹ PDP sponsors' compliance officers are responsible for developing, operating, and monitoring the organization's fraud, waste, and abuse program, yet 63 plans did not state that the compliance officer or another individual or group is specifically responsible for maintaining the sponsor's antifraud program, as required. An organization's compliance officer serves as the focal point for compliance activities and an organization's

compliance committee typically advises the compliance officer and assists in the implementation of the compliance program.

Internal monitoring and auditing. Seventy-one compliance plans did not address all requirements for the internal monitoring and auditing element. Fifty-two of these seventy-one plans addressed only one or two of the five requirements for the internal monitoring and auditing element.

PDP sponsors are required to monitor and audit their contractors' activities regarding the administration and delivery of the Part D benefit and to ensure that contractors' records are available for Government review. (We use the term contractors to indicate organizations that CMS's manual chapter refers to as "first-tier entities" or "downstream entities.") Forty-four compliance plans did not indicate that sponsors have procedures in place to monitor and audit their contractors' activities. In addition, 64 plans did not indicate that sponsors' contractors would provide their records to CMS or its designee. CMS is required to conduct audits to confirm sponsors' compliance with Part D contracts; however, 48 plans did not indicate that sponsors would allow CMS or other Government authorities to audit their records. While these results do not suggest that sponsors or their contractors would not provide requested records, the compliance plans contained no information relating to these requirements.

An ongoing monitoring and auditing process is critical to a successful compliance program because it enables an organization to identify and respond to compliance issues timely and to assess whether compliance plan elements are functioning appropriately (e.g., whether employees are completing compliance training, whether compliance policies have been distributed or made available).

Over half of compliance plans did not contain detailed information for each of six requirements involving compliance processes or programs

While sponsors' compliance plans in some way addressed certain CMS compliance plan requirements, the majority of plans did not contain details about how sponsors would implement these requirements. Details about the implementation of various compliance plan requirements are essential for ensuring that a compliance plan is actually functioning within an organization.

More than half of compliance plans that addressed each of six requirements we reviewed involving compliance processes or programs did not contain detailed information for these requirements. These requirements correspond to four of the eight compliance plan elements. The six requirements are: compliance training programs, processes for

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reporting compliance violations, internal monitoring and auditing procedures, contractor monitoring and auditing procedures, procedures for responding to compliance violations, and procedures for implementing corrective actions. The number of plans that did not address each requirement in detail is presented in Table 1 of Appendix A.

Compliance training programs. All but one compliance plan (78 of 79) addressed compliance training and education programs, but more than half of these plans (41 of 78) did not include any details regarding these programs. One compliance plan only indicated that the sponsor was currently working on a training plan. Another plan stated that the sponsor will update its compliance training program based on legal and regulatory requirements; however, the plan provided no detailed information about the content of the sponsor's training program. Compliance training programs are critical to ensuring that appropriate information regarding compliance plans and specific risk areas is communicated to individuals throughout an organization. Effective compliance plans include the following types of information regarding sponsors' compliance training programs: the topics to be covered, the format of the training, and the consequences to employees of their failure to participate in compliance training.

Processes for reporting compliance violations. Seventy-five of seventy-nine compliance plans indicated that sponsors have systems to communicate information throughout their organizations about reporting compliance concerns and misconduct. However, 44 of these 75 plans did not provide substantive descriptions of sponsors' reporting systems. For example, one plan simply stated that the compliance officer would be available to employees and contractors to clarify compliance policies and procedures, but did not provide detailed information regarding the sponsor's reporting systems. Organizations should have mechanisms in place for the reporting of improper conduct so that such allegations may be reviewed and addressed as appropriate. It is essential that reporting systems be clearly communicated to employees and contractors so that they can make effective use of these systems when necessary.

Internal and contractor monitoring and auditing procedures. All but one compliance plan addressed sponsors' internal monitoring and auditing procedures in some way, but more than half of these plans (44 of 78) did not describe monitoring and auditing procedures in detail. For example, one plan only noted that the sponsor uses audits to monitor compliance and prepares an annual compliance work plan with audit schedules. The plan did not include the audit schedule or any additional information about the

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the sponsor's monitoring and auditing program. Of the 35 compliance plans that mentioned sponsors' efforts to monitor contractors' activities, 26 plans did not describe sponsors' procedures for monitoring and auditing contractors' performance in detail. An ongoing evaluation process is critical to a successful compliance program. An effective compliance plan includes an auditing schedule and identifies the auditing and monitoring techniques that will be used by an organization and the areas that will be subject to audit.

Procedures for responding to compliance violations. All 79 compliance plans indicated that sponsors have procedures in place for ensuring prompt response to detected offenses and for developing and implementing corrective actions. However, 43 plans did not describe these procedures. For example, one plan merely stated that the compliance officer is responsible for requesting an investigation of a suspected violation of the law or the sponsor's compliance policy. Another plan only stated that the sponsor would conduct an investigation as promptly as practicable when a violation is reported.

Detected but uncorrected compliance violations can seriously endanger the mission, reputation, and legal status of an organization. The development of procedures for conducting timely and reasonable inquiries into reported misconduct and responding to the results of such inquiries is critical to ensuring that organizations respond appropriately to suspected noncompliance.

Procedures for implementing corrective actions. Fifty-four of seventy-nine compliance plans did not provide detailed descriptions of the types of corrective actions sponsors undertake in response to compliance violations. Some of these plans offered only brief, general statements regarding sponsors' corrective actions. For example, several plans indicated that sponsors' employees are subject to “. . . disciplinary action up to and including termination . . .” in response to compliance violations. Effective compliance programs include guidance regarding disciplinary actions for compliance violations.

While all compliance plans addressed the fraud and abuse element in some way, only 15 of 79 plans addressed all 11 recommendations that we reviewed regarding fraud detection, correction, and prevention

While all plans in some way addressed at least 2 of the 11 CMS recommendations that we reviewed regarding the development of a

comprehensive fraud and abuse plan, only 15 plans addressed all 11 selected recommendations. At the median, plans addressed 7 of these 11 recommendations. The eighth compliance plan element set forth in Part D regulations requires PDP sponsors to have “a comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse.”¹² CMS’s manual chapter, issued in April 2006, contains a number of recommendations regarding the overall design of PDP sponsors’ compliance plans. We selected 11 of these recommendations that were specific to fraud detection, correction, and prevention and determined whether sponsors’ compliance plans addressed them. The number of plans that did not address each recommendation selected for review is presented in Table 2 of the Appendix.

Sponsors’ efforts to detect fraud and abuse are essential to the integrity of the Part D benefit. Of the 79 compliance plans reviewed, 14 did not indicate that sponsors have any procedures in place to identify fraud, waste, and abuse. In addition, analysis of claims and other data is a key activity in identifying fraud,¹³ yet 28 compliance plans did not indicate that sponsors conduct any analysis of program data to examine trends, identify potential errors, or detect fraud. Effective compliance plans include specific techniques that are utilized to monitor an organization’s activities for potential fraud and abuse, procedures for conducting reviews of identified issues, and policies and procedures for responding to identified noncompliance.

Nineteen of seventy-nine plans did not indicate that sponsors have policies and procedures in place for coordinating and cooperating with CMS and law enforcement entities. CMS’s manual chapter includes a recommendation that sponsors have procedures to voluntarily report fraud or misconduct to Government authorities such as OIG or the Department of Justice, yet 19 plans did not indicate that sponsors have such procedures in place.

Forty-six compliance plans did not indicate that sponsors addressed CMS’s recommendation that their compliance training programs educate employees on fraud and abuse laws. Fifty compliance plans did not indicate that sponsors have methods to educate their enrollees on fraud,

waste, and abuse. Educating employees and enrollees is a key component to ensuring that such individuals recognize and know how to report potential fraud and abuse and compliance violations.

Even when compliance plans addressed certain CMS recommendations, over 40 percent did not include detailed information

In addition to determining whether sponsors' compliance plans addressed CMS's recommendations in any way, we also determined whether plans included detailed information for six recommendations regarding the establishment of fraud detection, correction, and prevention procedures. Over 40 percent of plans that addressed the 6 recommendations did not contain detailed information for each of the recommendations. A compliance plan should include detailed and specific policies and procedures for how the various plan elements will be implemented in order to operate as a functioning and effective compliance program.

Sixty-five of seventy-nine plans indicated that sponsors have procedures in place for the identification of fraud, waste, and abuse, but 28 of the 65 plans (43 percent) included only basic references to these procedures. Thirteen of these twenty-eight plans made brief references to the sponsor's fraud hotline, or to fraud, waste, and abuse training. Another five plans stated only sponsors' intentions to address fraud, waste, and abuse in the future. Forty-three of seventy-nine plans indicated that sponsors have processes to identify overpayments or repay such overpayments, yet 41 of the 43 plans (95 percent) did not describe these processes in any detail.

Fifty-one of seventy-nine plans indicated that sponsors conduct data analysis to detect fraud. Thirty-seven of these 51 plans (73 percent) did not include descriptions of data analysis processes or methods to identify errors and questionable data patterns.

Twenty-nine plans indicated that sponsors have methods to educate their enrollees on fraud, waste, and abuse. However, 19 of these plans (66 percent) did not describe sponsors' education methods in detail.

Sixty-nine of seventy-nine plans indicated that sponsors have monitoring and auditing procedures that test sponsors' compliance with laws, regulations, and internal policies, but 40 of the 69 plans (58 percent) did not provide descriptions of these procedures to protect against potential fraud and abuse. Sixty of seventy-nine plans indicated that sponsors have policies and procedures in place for coordinating and cooperating with CMS and law enforcement entities. Of these, 46 plans (77 percent) did not describe sponsors' policies and procedures for such coordination and cooperation.

► R E C O M M E N D A T I O N

This report provides results of our early review of PDP sponsors' compliance plans. When implemented successfully, a compliance plan that includes a comprehensive fraud, waste, and abuse program helps sponsors protect the integrity of Medicare funds and may also improve the operating efficiency and effectiveness of sponsors' PDPs.

We found that all PDP sponsors have compliance plans. However, these plans have not fully addressed all of the requirements that CMS specified in its guidance documents for the eight required compliance plan elements. In addition, our findings suggest that certain PDP sponsors' compliance plans contain only the broad outlines of a fraud and abuse plan. These compliance plans do not include descriptions of specific processes to implement and monitor a fraud and abuse plan. Effective compliance plans should include detailed and specific policies and procedures for how plan elements will be implemented.

CMS has not specifically audited PDP sponsors' compliance plans or fraud, waste, and abuse programs to determine whether sponsors have addressed the eight elements established by regulation. Therefore, CMS should:

Ensure that PDP sponsors' compliance plans address all requirements.

The manual chapter issued by CMS in April 2006 includes both required and recommended provisions regarding compliance plan elements. CMS should ensure that sponsors' compliance plans address all requirements presented in its manual chapter regarding the eight elements set forth in regulation. CMS should also encourage sponsors to provide sufficient detail in their compliance plans to clearly demonstrate how sponsors are actually implementing the compliance plan requirements.

AGENCY COMMENTS

CMS agreed that effective compliance plans are an important tool for monitoring fraud, waste, and abuse in PDP sponsors' Part D plans and concurred with OIG's recommendation. CMS stated that it stands ready to take appropriate action against any plan that fails to respond to its concerns.

CMS also provided additional comments and context on some issues in the report. CMS stated that the short timeframes for implementing many new provisions of the Medicare Prescription Drug, Improvement, and Modernization Act may have had an impact on how thorough documents, such as compliance plans, were. CMS also stated that, although

R E C O M M E N D A T I O N S

compliance plan audits will not begin until January 2007, CMS account managers have been conducting routine compliance efforts with PDP sponsors since the start of the Part D program. CMS stated that the routine audits beginning in 2007 will review the required compliance plan elements and that sponsors will be accountable for meeting all requirements.

CMS stated that it would not be possible for compliance plans to address all 17 requirements to the extent that these requirements were found in the April 2006 manual chapter because OIG reviewed compliance plans that sponsors provided between November 2005 and January 2006.

CMS also suggested modifying language in the report concerning PDP sponsors' voluntary reporting of possible fraud or misconduct to Government authorities, such as OIG or the Department of Justice.

The complete text of CMS's comments can be found in Appendix C.

OFFICE OF INSPECTOR GENERAL RESPONSE

CMS's planned audits, as described, address our recommendation. In addition, OIG acknowledges the efforts CMS described to ensure that PDP sponsors comply with requirements on a range of issues and we have revised language in our recommendation section accordingly.

We have revised language in the report concerning PDP sponsors' procedures for voluntarily reporting misconduct to Government authorities. We also revised wording in the report to clarify that the 17 requirements included in our review were contained in the summary document issued to PDP sponsors in June 2005. These requirements were later included in CMS's manual chapter as well. Therefore, the PDP sponsors' compliance plans should have addressed the 17 requirements at the time of our review.

Table 1. Number of Compliance Plans That Did Not Address 17 CMS Requirements for the Eight Compliance Plan Elements

Compliance plan requirements	Plans did not address the requirement	Plans addressed the requirement in some way	Plans addressed the requirement, but not in detail NR=Not Reviewed
Element 1: Written policies, procedures, and standards of conduct			
1. Sponsor has written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.	0	79	NR
Element 2: Compliance officer and compliance committee			
2. Sponsor has a compliance officer in place.	12	67	NR
3. Sponsor has a compliance committee in place.	11	68	NR
4. Sponsor has established a compliance committee that is overseen by the compliance officer, advises the compliance officer, and assists in the implementation of the compliance program.	16	63	NR
5. Compliance officer is responsible for developing, operating, and monitoring the fraud, waste, and abuse program.	63	16	NR
Element 3: Compliance training and education			
6. Sponsor has a training and education program in place.	1	78	41
Element 4: Lines of communication			
7. Sponsor has established lines of communication to provide organization-wide information about how to report compliance concerns and suspected or actual misconduct.	4	75	44
8. Sponsor has mechanisms in place for capturing concerns and risks, such as hotlines, suggestion boxes, or employee exit interviews.	4	75	NR
Element 5: Disciplinary guidelines			
9. Sponsor enforces standards through disciplinary guidelines.	4	75	NR
Element 6: Internal monitoring and auditing			
10. Sponsor has an internal monitoring and auditing program.	1	78	44
11. Sponsor has a plan in place to monitor and audit contractors' responsibilities and activities.	44	35	26
12. When requested, sponsor is prepared to allow CMS to audit its financial records.	48	31	NR
13. Sponsor allows access to any auditor acting on behalf of the Federal Government or CMS to conduct an onsite audit.	58	21	NR
14. Sponsor's contractors provide records to CMS or its designee.	64	15	NR

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Compliance plan requirements	Plans did not address the requirement	Plans addressed the requirement in some way	Plans addressed the requirement, but not in detail NR=Not Reviewed
Element 7: Response to offenses and corrective actions			
15. Sponsor has procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives.	0	79	43
16. Sponsor conducts appropriate corrective actions in response to potential violations.	0	79	54
Element 8: Comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse			
17. Sponsor has a comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse.	0	79	NR

Table 2. Number of Compliance Plans That Did Not Address 11 Selected CMS Recommendations Regarding Sponsors’ Fraud and Abuse Plans

Compliance plan recommendations*	Plans did not address the recommendation	Plans addressed the recommendation in some way	Plans addressed the recommendation, but not in detail NR=Not Reviewed
Element 8: A comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse			
1. Sponsor has procedures for the identification of fraud, waste, and abuse in its network.	14	65	28
2. Sponsor has a process to identify overpayments at any level within its network and to properly repay such overpayments in accordance with CMS policy.	36	43	41
3. Sponsor has policies and procedures for coordinating and cooperating with MEDICs, CMS, and law enforcement, including policies that fully cooperate with any audits conducted by the abovementioned entities or their designees.	19	60	46
4. Sponsor’s compliance officer’s duties include responding to reports of potential and actual instances of Part D fraud, waste, or abuse, including the coordination of internal investigations and the development of appropriate corrective or disciplinary actions.	4	75	NR
5. Sponsor’s compliance officer’s duties include maintaining documentation for each report of potential fraud, waste, or abuse received through any of the reporting methods (i.e. hotline, mail, in-person) which summarizes the initial report of noncompliance, the investigation, the results of the investigation, and all corrective and/or disciplinary action(s) taken as a result of the investigation.	12	67	NR
6. Sponsor’s compliance training addresses pertinent laws related to fraud and abuse.	46	33	NR
7. Sponsor has various methods to educate enrollees on prescription drug fraud, waste, and abuse.	50	29	19
8. Sponsor has procedures for internal monitoring and auditing to test and confirm compliance with the Part D benefit regulations, subregulatory guidance, contractual agreements, and all applicable State and Federal laws, as well as internal policies and procedures to protect against potential fraud, waste, or abuse.	10	69	40
9. Sponsor receives and reviews at least one of the following data reports: payment reports, drug utilization reports, prescribing patterns by physician reports, geographic ZIP reports.	38	41	NR
10. Sponsor conducts data analysis that includes the comparison of claim information against other data (e.g., provider, drug provided, diagnoses, or beneficiaries) to identify potential errors and/or potential fraud.	28	51	37
11. Sponsor has procedures in place to voluntarily self-report potential fraud or misconduct to Government authorities such as OIG (through OIG’s Provider Self-Disclosure Protocol) or the Department of Justice.	19	60	NR

*CMS’s manual chapter specifies recommendations for designing the fraud and abuse plans outlined in Element 8. We reviewed compliance plans to determine whether they addressed 11 recommendations specific to fraud detection, correction, and prevention that we selected for review.

▶ A P P E N D I X ~ C



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: DEC - 4 2006

TO: Daniel R. Levinson
Inspector General

FROM: Leslie V. Norwalk, Esq.
Acting Administrator

SUBJECT: Office of the Inspector General (OIG) Draft Report, "Prescription Drug Plan Sponsors' Compliance Plans" (OEI-03-06-00100)

The Centers for Medicare & Medicaid Services (CMS) has reviewed the OIG draft report entitled *Prescription Drug Plan Sponsors' Compliance Plans*. We appreciate the information, and we agree that effective compliance plans are an important tool to monitor fraud, waste and abuse in contracted Prescription Drug Plans.

While CMS has not specifically audited Part D sponsors' internal compliance plans to date, CMS account managers have conducted routine compliance efforts with prescription drug plan sponsors since the start of the Part D program in January 2006. Moreover, in January 2007 CMS will begin routine audits of PDP sponsors. These audits will enable CMS to assess the effectiveness of PDP compliance plans. Numerous compliance letters have been issued regarding a range of topics, including: call center performance, inaccurate data on the Medicare Personal Drug Plan Finder, and inadequate exceptions and appeals-related information on sponsors' websites. In most cases, these actions have resulted in timely responses by the drug plans. Cases when plans did not resolve issues promptly have resulted in further enforcement actions to achieve compliance, such as restricting plans' ability to enroll beneficiaries. One plan with recurrent service problems has been placed on a track that may result in termination. Consistent with how we handle evidence of non-compliance brought to our attention, CMS account managers will follow up with sponsors identified in the OIG report to ensure that sponsors take steps to correct their compliance plan deficiencies.

We would also note that the checklist requirements OIG used were based on the June 2005 summary document and the Fraud, Waste and Abuse manual chapter issued in April 2006. However, the compliance plans OIG evaluated were from November 2005 and January 2006 – prior to the April 2006 publication which contained many of the checklist requirements. Therefore, it would not be possible for these compliance plans to contain all 17 requirements to the extent these requirements were found in the April 2006 manual chapter.

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GENERAL

CMS would like to offer the following comments to specific sections of the report:

1. Background - The report indicates the Medicare Modernization Act (MMA) was passed in 2003, but does not reference the fact that implementation of many *new* provisions had to occur within very tight timeframes. These short timeframes can affect how thorough certain documents, like compliance plans, might be.
2. Recommendations - The report states in the recommendations that “there is little oversight of sponsors’ compliance efforts at this time.” CMS account managers work on a daily basis to ensure that plan sponsors are carrying out their obligations to CMS.

OIG Recommendation #1

CMS should ensure that sponsors’ compliance plans address all requirements presented in its manual chapter regarding the eight elements set forth in regulation.

CMS Response

We concur with this recommendation. Included in CMS’ Part D Audit Guide is a section on Compliance Plans which includes a review of the eight required compliance plan elements. CMS will begin these compliance plan audits in 2007, and sponsors will be accountable for meeting all requirements.

OIG Recommendation #2

CMS should also encourage sponsors to provide sufficient detail in their compliance plans to clearly demonstrate how sponsors are actually implementing the compliance plan requirements.

CMS Response

We concur with this recommendation. As part of our compliance plan audits, CMS will review how sponsors are actually implementing the compliance plan requirements. Although, sponsors have significant flexibility regarding how they implement the recommendations set forth in *Chapter 9 of the Part D Manual – Part D Program to Control Fraud, Waste and Abuse*, CMS anticipates including as part of our compliance plan audits the tracking of compliance “Best Practices” and “Areas for Improvement.” We plan to use this information to update future compliance requirements and recommendations and potentially share this data for education purposes with all sponsors.

3. Page 9 – The report states that, “Almost one-third of plans did not specifically refer to the Part D benefit with respect to the eight compliance plan elements.” CMS believes that if the compliance plan sufficiently addresses the required areas, and covers Part D plans, specifically mentioning the Part D benefit is not necessary.

Page 3 – Daniel R. Levinson

4. Page 13, 3rd paragraph, 2nd sentence - CMS suggests modifying the language as follows:

CMS's manual chapter includes a recommendation that sponsors have procedures to voluntarily self-report potential fraud or misconduct to Government authorities such as OIG or the Department of Justice, yet 19 plans did not indicate that sponsors have such procedures in place.

5. Page 13, 3rd paragraph., 2nd sentence on pg.7 in Table 2, no. 11 - CMS suggests modifying the language as follows:

Sponsor has procedures to voluntarily self-report potential fraud or misconduct to Government authorities such as OIG (through OIG's Provider Self-Disclosure Protocol) or the Department of Justice.

We appreciate the efforts of the OIG, and we stand ready to take appropriate action against any plan that fails to respond to our concerns. We believe our actions thus far demonstrate our ability to work with our contractors to that end, and we will continue in these efforts. We look forward to working with the OIG as we proceed to address this issue, for the well-being of all Medicare and Medicaid beneficiaries.

► E N D N O T E S

¹“Medicare Coverage—General Information.” Centers for Medicare & Medicaid Services (CMS). December 2005. Available online at <http://www.cms.hhs.gov/CoverageGenInfo/>. Accessed April 10, 2006, p. 1.

²“Medicare Prescription Drug Benefit Fact Sheet.” Henry J. Kaiser Family Foundation. May 2006. Available online at <http://www.kff.org/medicare/upload/7044-03-2.pdf>. Accessed May 16, 2006, p. 2.

³“Medicare Prescription Drug Benefit: Solicitation for Applications from Prescription Drug Plans (PDPs).” CMS. January 21, 2005, as revised on March 9, 2005, p. 4.

⁴“Total Medicare Beneficiaries with Drug Coverage Data (v06.11.06).” CMS. June 2006. Available online at http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/02_EnrollmentData.asp. Accessed June 15, 2006.

⁵“Medicare Prescription Drug Benefit: Solicitation for Applications from Prescription Drug Plans (PDPs).” CMS. January 21, 2005, as revised on March 9, 2005, pp. 2–4.

⁶ 42 CFR § 423.504(b)(4)(vi).

⁷ Ibid.

⁸“Medicare Prescription Drug Benefit: Solicitation for Applications from Prescription Drug Plans (PDPs).” CMS. January 21, 2005, as revised on March 9, 2005, p. 15.

⁹“Fraud Prevention & Detection—Compliance Guidance.” U.S. Department of Health and Human Services, Office of Inspector General. Available online at <http://oig.hhs.gov/fraud/complianceguidance.html>. Accessed April 28, 2006.

¹⁰ 42 CFR § 423.504(b)(4)(vi).

¹¹ Ibid.

¹² Ibid.

¹³“Prescription Drug Benefit Manual: Chapter 9—Part D Program to Control Fraud, Waste and Abuse.” CMS. April 2006, p. 43.



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

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