



Medicare Part D Detection, Evaluation Review and Action Plan *Detect, Correct and Prevent*

Lena Robins, Foley & Lardner LLP
Susan Roberts, ATTAC Consulting Group, LLC

Medicare Compliance and Operations Summit 2007 –
July 18, 2007

©2007 Foley & Lardner LLP • Attorney Advertising • Prior results do not guarantee a similar outcome • Models used are not clients but may be representative of clients • 321 N. Clark Street, Suite 2800, Chicago, IL 60610 • 312.832.4500



The FWA Requirement

- Part D sponsors must have in place a comprehensive plan to detect, correct, and prevent fraud, waste, and abuse (“FWA”)

42 C.F.R. § 423.504(b)(4)(vi)(H)



CMS Guidance

- Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste, and Abuse (April 2006)
- CMS Summary Document, “Review of Sponsors’ Fraud, Waste, and Abuse Responsibilities” (June 2005)

3



CMS Enforcement

- Medicare Drug Integrity Contractors (MEDICs)
 - Purpose is to assist CMS in management of audit, oversight, and anti-fraud and abuse efforts in Part D program
 - Tasked with identifying cases of suspected fraud and developing cases in timely manner

4



Regional MEDICs

- Three regional MEDICs divided geographically
 - West MEDIC (SACI), North MEDIC (EDS), Southeast MEDIC (Delmarva/Health Integrity LLC)
- Responsible for audits, data analysis, investigations, special projects, complaint follow-up, and education and outreach

5



OIG Review

- “Prescription Drug Plan Sponsors” Compliance Plans (OEI-03-06-00100) (December 2006)
- Reviewed compliance plans submitted by 79 PDPs
- Focused on 17 recommendations in Summary Document (only guidance available at time of OIG review) and 11 recommendations from Chapter 9
- 17 recommendations are associated with 8 regulatory compliance elements

6



OIG Review

- All PDPs had a compliance plan, but:
 - 72 of 79 plans did not address all the CMS requirements regarding 8 compliance plan recommendations
- All plans addressed the fraud and abuse element, but:
 - Only 15 of 79 plans addressed all 11 recommendations regarding fraud detection, correction, and prevention

7



OIG Review (cont'd)

- The report finds that many plans simply restated certain requirements outlined by CMS, and *did not describe specific processes to put in place and monitor a fraud and abuse plan*
- OIG investigators deemed these to be instances of noncompliance

8



CMS Follow Up

- Health Plan Management System Memo to PDP Sponsors (June 11, 2007)
- CMS requested all PDPs to complete Compliance Plan Best Practices Self-Assessment by June 25, 2007
- Tool will enable CMS to assess the degree to which requirements and best practices in Chapter 9 have been implemented to date

9



Key Components for Compliance Success

- Achievement in a Part D compliance program assures:
 - A disciplined approach--
 - To compliance with the applicable laws and regulations and
 - To the implementation of an effective program to detect, correct, and prevent FWA
 - An effective Part D compliance program will make effective use of the organization's existing compliance and fraud and abuse programs
 - Particularly important is the *integration* of audit and internal controls with ethics and compliance

10



Definition

- An effective Part D compliance program requires:
 - Establishment of policies and procedures to implement Part D requirements,
 - Effective training of employees, directors, and subcontractors, and
 - A robust program to detect, correct, and prevent FWA

11



What Are Policies and Procedures? Why Are They Important?

- Policies and Procedures
 - Roadmap to success
 - Provide clarity and direction rather than confusion and unknowns
 - One document for *all to follow*
 - *CMS requirement*

12



Policies and Procedures

- Written policies and procedures should address the major components of a Part D program, including:
 - Benefit design, including the pharmacy and therapeutics committee, utilization management standards, quality assurance and patient safety, medication therapy management, and electronic prescriptions
 - Pharmacy access, including retail pharmacies, out-of-network access, mail order, home infusion, and Indian Health Service, Indian Tribe and Tribal Organizations, and Urban Indian Organization I/T/U pharmacies
 - Enrollment and eligibility, including special enrollment periods, retroactive enrollment, disenrollment (voluntary and involuntary)

13



Policies and Procedures (cont'd)

- Grievances, including expedited reviews and member materials.
- Exceptions and appeals, including expedited appeals, levels of review, notice of adverse determinations, and member materials
- Coordination of benefits, including user fees
- Tracking Out-of-Pocket Costs (TrOOP), including monthly reports to members, member access via phone, and status at disenrollment
- Marketing and beneficiary communications, including legal and business reviews and oversight of marketing materials, enrollee information, call center operation, web access, and EOBs

14



Policies and Procedures (cont'd)

- Provider communications
- Reporting requirements, including significant business transactions, claims data, discounts and rebates, UM data, appeals, medication therapy management data, pricing and pharmacy network information, and conflict of interests
- Data exchange with CMS, including monthly enrollment, disenrollment, and change transactions and enrollment/payment reconciliations
- Privacy, including disclosure to beneficiaries of PHI policies
- Security and record retention
- Claims processing, including in-network and out-of-network claims, mail order claims, claims data retention, audit trails, handling of overpayments/underpayments, etc.

15



Define the Compliance Plan

- Policies and procedures establish:
 - Part D Plan's cooperation and coordination with CMS and the organizations designated by CMS, including MEDICs, responsible for assisting PDPs with detection, correction, and prevention of FWA
 - Part D Plan's commitment to detect, correct, and prevent FWA

16



Commitment to Prevent, Detect and Correct FWA

- Policies and Procedures must describe or require:
 - Written standards of conduct to be distributed to employees at time of hire, to subcontractors at time of contract, when standards are updated, and annually thereafter. As a condition of employment, employees must certify that they have read and will comply with the standards
 - Employees and subcontractors sign statement related to conflict of interests at time of hire or contract and annually thereafter

17



Commitment to Prevent, Detect and Correct FWA (cont'd)

- Part D Plan to review exclusion lists periodically to ensure that employees and subcontractors are not on such lists and that the appropriate employment and contracting actions are taken for employees or contractors appearing on such lists
- How overpayments in the network are identified and repayments made to CMS
- How Part D plan identifies FWA in the network and reports incidents as appropriate, internally and/or externally, for investigation

18



Commitment to Prevent, Detect and Correct FWA (cont'd)

- How Part D plan coordinates and cooperates with CMS, MEDICs, and law enforcement agencies in conducting audits and investigations
- How Part D plan performs data requests for CMS, MEDICs, and law enforcement agencies
- How Part D plan maintains records for 10 years
- How Part D plan ensures full disclosure of pricing decisions and clear guidance on documentation of decisions. Includes steps to prevent receipt or provision of benefits on commercial business in consideration of Part D formulary decisions
- How Part D plan maintains commitment to legal and ethical P&T Committee decisions and formulary decisions

19



Why Perform Oversight of Policies and Procedures?

- Consistent, effective oversight is critical to stay on the right path
 - Conduct an annual risk assessment to target critical policies
 - Develop monitoring and auditing programs to assess compliance with key policies
 - Issue internal CAPs with clear action plans to address deficiencies
 - Ensure policy development and oversight are critical components of overall compliance plan

20



Effective Monitoring and Auditing

- Is management kept apprised of regulatory and industry developments affecting the organization's compliance risks?
- Are contracts reviewed for legal sufficiency and compliance with program requirements?
- Are there quality controls to ensure accurate TROOP and LIS accounting?
- Are systems in place to ensure accurate and complete reports to CMS?

21



Effective Monitoring and Auditing

- Review of high risk areas, such as beneficiary enrollment and marketing
- Unannounced internal audits or "spot checks"
- Review of areas previously found non-compliant to determine if the corrective actions have fully addressed the underlying problem
- Use of objective independent auditors with knowledge of Part D requirements
- Monitoring and oversight that addresses fraud and abuse with subcontractors, such as the plan's pharmacy network and PBMs

22



Integrating Compliance Auditing Efforts

- Gaps in readiness should be number one focus initially:
 - Identify key processes and map related business steps
 - Develop action plans to address gaps
 - Re-review areas of gaps to verify they are resolved
- Ongoing auditing and monitoring. Incorporate different risk areas into daily monitoring activities, *i.e.*, enrollment eligibility check lists, payment reconciliations, etc.
- Auditing plan should include risk areas which have greatest likelihood to occur and are least managed

23



Identifying Compliance Problems

- Compliance issues can come from number of different sources:
 - Employee hotline
 - Customer complaints
 - Baseline audits
 - Reports to Compliance Officer

24



How Can an Employee Identify a Part D Compliance Issue?

- Employees should know and understand the Part D rules so that they can identify potential fraud and abuse issues. Some examples involving Part D plans include:
 - Employees involved in contract negotiations with pharmaceutical manufacturer and pharmacy benefit managers should be aware of improper rebates, price concessions, or other inducements that may implicate the Federal False Claims Act and/or the Anti-Kickback Statute

25



How Can an Employee Identify a Part D Compliance Issue? (cont'd)

- Employees involved in marketing activities should be aware of improper inducements offered to beneficiaries to convince beneficiaries to select a particular plan that could violate the Beneficiary Inducement Civil Monetary Penalty Law
- Employees involved in formulary and P&T Committee activities should be aware of improper practices with pharmaceutical manufacturers, such as enhanced formulary placement, that are designed to obtain more favorable treatment of the manufacturer's products and could potentially violate the Federal Anti-Kickback Statute

26



Evaluating Problems

- Written policies and procedures that represent sponsor's response to day-to-day risks. Includes sponsor's network
- Policies and procedures should contain a Code of Conducts/Ethics and address all aspects of a Part D sponsor's business operations and potential fraud and abuse areas
- Policies and procedures should contain processes for identifying overpayments at any level within the plan and corrective action initiatives
- Policies and procedures should address coordination and cooperation with the MEDICs, CMS, OIG, and other government enforcement agencies

27



Response: Righting the Wrong

- Sponsors can develop effective correction action plans by proactively and timely responding to detected deficiencies
- Creation of proper investigation team
- Conduct prompt and thorough investigation
- Create and implement corrective action plan

28



Response to Detected Violations

- How do we evaluate and respond to suspected compliance violations?
- How do we identify and preserve relevant documents and information?
- What guidelines exist for reporting compliance violations to senior management, the board, the MEDICS, and the government?
- Do we establish or change internal controls in response to audit findings?

29



When to Involve Legal Counsel?

- Legal counsel can direct investigation such that it is protected under the attorney-client privilege
- “Privilege” is a rule of evidence that bars certain communications from admission in a legal proceeding. Encourages full and frank communication and protects documents, work papers, etc.
- The organization holds the privilege

30



Investigation: Privilege?

- Ordinary auditing and monitoring vs. privileged audits and investigations
- Risk analysis
- Will depend upon specific facts, identified risk area, and potential exposure
- If decide to conduct investigation under privilege, get legal counsel involved *early*. Timing is key

31



Practical Challenges

- “Bad paper”
 - Documentation of issues in a negative manner
- Privilege issues
 - Established too late
 - Could be waived, voluntarily or involuntarily
- Staffing Issues
- Who will make up the investigative team, e.g., internal staff, outside consultants, accounting firm, law firm?

32



Enforcing the Standards

- Sponsors can help create an organizational culture that fosters ethical and compliant behavior by consistently enforcing disciplinary standards
 - Standards are well publicized
 - Consistently enforced
 - Exclusion lists checked
 - Emphasis on non-retaliation

33



Enforcing the Standards (cont'd)

- Are all employees held accountable and incentivized to meet compliance-related standards during performance reviews?
- Are contractors held accountable for meeting these compliance standards during contract renegotiations?
- Is there a published range of disciplinary actions that may be imposed for noncompliance?

34



Enforcement and Discipline

- Sanctions for non-compliant behavior
- Consistency
- Stand firm
- OIG sanctions reviews
- Incentives

35



Case Scenario 1

- Federated Insurance Company offers several Part D benefit products, including a benefit where patients do not pay any deductibles and all of their generic-name medications and certain brand-name drugs are covered until they reach government-subsidized coverage. This “Premium Plan” costs Medicare beneficiaries \$60 a month in premiums, not including co-payments. Federated staffs a national call center to enroll patients and answer questions about its drug benefit options. Call center workers Smith and Jones have previously trained on informational items that must be covered in the course of telephone conversations with potential Medicare beneficiaries. Federated has implemented a computerized scripting program, provides the call center members with the information and instructs them on what to say to a patient at a given moment, thus ensuring uniformity of message. Smith finds the new system too cumbersome to use and instead chooses to use an old checklist format. Jones uses the automated system and witnesses Smith offering callers \$25 gift certificates to restaurant chains if they sign up with the Premium Plan. Jones reports this directly to the compliance officer. What should she do?

36



Case Scenario 2

- Lisa and Jane are members of a call center sales force for American Insurance Company, a national PDP plan sponsor. There has been much competition on the floor of the call center over how many potential beneficiaries are enrolled by each staff. American has announced an incentive program for all members of the call center. American will pay higher sales commissions to call center representatives who enroll beneficiaries in one of American's MA-PDs rather than in its standalone PDP. Lisa thinks this is just the inspiration she needs to enroll members in record numbers. Jane is concerned that American's incentive could be a violation of the Part D Marketing Guidelines. Is the action by the plan sponsor proper? What can Lisa do to appropriately express his concerns?

37



Questions & Answers?

38



Contact Us

Lena Robins
Foley & Lardner LLP
3000 K St. N.W.
Suite 500
Washington, D.C. 20007
Tel: 202.295.4790
Fax: 202.672.5399
lrobins@foley.com

Susan Roberts
ATTAC Consulting, LLC
3111 W. Dr. Martin Luther
King Jr. Blvd.
Suite 100
Tampa, FL 33607
Tel: 813.651.9047
Fax: 813.684.2431
srobert@attacconsulting.com