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**Medicare Part D: Prescription Drug Benefit**


MMA Implementing regs: 70 Fed. Reg. 4, 193 (Jan.28,2005); 42 CFR Part 423

CMS Website: [http://www.cms.hhs.gov/PrescriptionDrugCovGenin/](http://www.cms.hhs.gov/PrescriptionDrugCovGenin/)

Chapter 9, Prescription Drug Benefit Manual, April 25, 2006
Employer Sponsors: A Summary

- The federal government will provide an estimated $4.6 billion in direct subsidies to employers, labor unions, and others for their prescription drug benefit plans to retirees in 2006.
- To qualify, organizations are required to adopt a comprehensive program to control fraud, waste, and abuse (FWA) that will be audited by or for the U.S. and will be subject to civil and criminal penalties.
  - An organization’s FWA program must be in place by January 1, 2007.
  - It can be incorporated into a company’s existing corporate compliance structure or operate on a stand alone basis.
Medicare provides a Retiree Drug Subsidy (RDS) to private sponsors of retiree prescription drug plans
- Medicare reimburses sponsors up to 28% of annual allowable costs between $250 and $5,000 in CY '06 of providing prescription drug coverage for plan members who are eligible to enroll in Part D but are not enrolled

Who/what can qualify as a Sponsor?
- Employers, unions, or any entity offering a qualifying prescription drug benefit
- A public or private entity:
  - Organized and licensed by a state as a risk-bearing entity (an insurance program)
  - Certified by the Centers for Medicare and Medicaid Services (CMS) as meeting the Medicare Advantage contract requirements, and
  - Provides qualified prescription drug coverage
- A capitated benefit program designed to provide comprehensive medical and social service for low-income individuals
Medicare Part D Prescription Drug Program

The Retiree Drug Subsidy: What does it mean to employers?

- General Motors paid $5.4 billion in health care costs for 141,000 workers, and 449,000 retirees and their dependents. This amounts to $1,500 in health care costs for every vehicle produced.

- The estimated annual value of RDS to an employer is about $766 per retiree for 2006. Extrapolated to GM, the estimated benefit can be worth as much as $343.9 million in 2006 alone, without regard to tax benefits.

- The RDS offers Sponsors an immediate financial and long-term competitive benefit.
The Retiree Drug Subsidy offers health care insurers and PBM’s a near-term multibillion new revenue opportunity

- Medco forecast $2 billion of incremental revenue from the new Medicare Prescription Drug Plan in 2006 in its business unit that covers Medicare and retiree drug services ($9.2 billion base)

- UnitedHealth expects $6 billion in new revenue, and WellPoint expects $1.4 billion from the Medicare Part D program in 2006 (these estimates include revenue from employer sponsors and other sources under the program)

- The Retiree Drug Subsidy also provides new opportunities to:
  - Cross-sell other products to the millions of new Part D subscribers
  - Convert them to the more lucrative Medicare Advantage portion of the Medicare Part D program
In order to qualify, Sponsors must implement a comprehensive program to prevent and detect fraud, waste and abuse

- The Sponsor’s anti-FWA plan may be:
  - A plan that is separate and in addition to other compliance plan components; or
  - Integrated into elements of an existing compliance plan

- However, there must be a separate compliance officer designated under the Part D program
Anti-Fraud, Waste, and Abuse Program Requirements

1. Written policies and procedures
2. Compliance officer and compliance committee
3. Training and education
4. Effective lines of communication
5. Enforcement of standards through well-publicized disciplinary guidelines
6. Monitoring and auditing
7. Corrective action procedures
8. Comprehensive fraud and abuse plan – procedures for self-reporting potential fraud and misconduct
Program Sponsor Responsibilities

- The Sponsor retains ultimate responsibility for complying with its contract with CMS, regardless of tasks delegated to subcontractors.
- The Sponsor will be held liable for any failure of its first tier and downstream subcontractors to comply with the CMS contract, regulations, and statutes.
- CMS may require the Sponsor to remove subcontractors if they fail to comply with the CMS contract, regulations, and statutes.
- Sponsors and subcontractors may be subject to administrative sanctions, recoupment, civil monetary penalties, civil and criminal prosecution for fraud in connection with delivery of Part D benefits:
  - False Claims Act
  - Anti-Kickback Statute
**Program Sponsor Responsibilities**

**Sponsors are subject to CMS triennial audits**

- The Health & Human Services – Office of Inspector General (HHS OIG) is responsible for conducting audits to ensure accuracy and correct payment.

- CMS must annually audit financial records of at least one-third of Part D Sponsors. Some of these audits will be conducted on-site.

- A Sponsor must be prepared to allow CMS to audit its financial records, including all data related to Part D utilization and costs.

- CMS will conduct **random desk audits** annually, which may overlap with triennial audits.

- CMS may engage subcontractors to conduct audits on its behalf.
Anti-FWA Program Life Cycle

1. Readiness Assessment
   - Incidents Investigation
   - Remediation on Recommendations and Findings

2. Design and Implementation Assistance
   - Reevaluate Risk
   - Annual Plan
   - Remediation on Recommendations and Findings

3. Operate and Monitor Program
   - Reporting
- The depth of the anti-FWA readiness assessment will be determined by the organization
- A subcontractor first-tier entity may want a deeper level of detail than an employer-sponsor
Part D Program Components

- Readiness Assessment
- Design Program
  - Identifying the Risks and Setting up the Infrastructure to Deal with Risks
- Operate and Monitor Program
  - Testing the Program
- Incident Investigation and Remediation
  - Corrective Action
- Reporting
Tasks

- Identify risks of FWA
- Identify general and process-specific procedures and controls to mitigate risks
- Define contractor/subcontractor responsibilities
- Report identified risks
- Develop annual work plan
- Develop protocol for investigating alleged FWA
**Tasks**

- Establish program infrastructure:
  - Compliance Officer
  - Compliance Committee
  - Training, including fraud awareness, Code of Conduct, procedures, controls, hotline and investigative protocol
  - Effective lines of communication
  - Policies and Procedures
  - Code of Conduct
Operate and Monitor Program

**Ongoing work plan requirements:**

1. Independent compliance/internal audit department
2. Regular schedule and written methodology
3. Regular audits of bids, pricing data, changes in drug prices, and data for determining risk, adjustments and true out of pocket costs
4. Assess compliance program performance
5. Random statistical sampling of sponsor facilities, pharmacies, and providers
6. Audit and monitor subcontractors
7. Use of data analysis for fraud prevention and detection

*Source: Prescription Drug Benefits Manual, Chapter 9*
Operate and Monitor Program

Tasks

- Develop and implement procedures and controls to prevent and detect FWA
- Conduct training, monitor completion of training requirements, and evaluate effectiveness
- Operate hotline and other reporting mechanisms
- Develop mechanisms to identify and bar subcontractors and employees who are on the HHS OIG exclusion list
- Monitor potential conflicts of interest
- Conduct data mining to identify fraud risk patterns and highlight specific transactions for investigation
Tasks

- Monitor the performance of the anti-FWA program
- Monitor performance of contractor/subcontractor anti-FWA responsibilities
- CMS expects that Sponsors will engage in internal monitoring and audits, as well as auditing the downstream entities for FWA.
- Maintain compliance documentation for 10 years
Incident Investigation and Remediation

Tasks

- Screen hotline calls, customer complaints, and employee grievances
- Track, analyze, and summarize complaints about providers
- Investigate allegations, resolve them, and report to Medicare Drug Integrity Contractor or CMS
- Take corrective actions to resolve specific incidents
- Identify control gaps and implement changes to policies and procedures
Tasks

- The Sponsor’s Part D Compliance Officer must report at least quarterly to Corporate Compliance Officer, Board of Directors, CEO, and Compliance Committee on:
  - Status of compliance program implementation
  - Identification/resolution of potential or actual instances of non-compliance
  - Sponsor’s oversight and audit activities
  - Objective measurements of compliance program performance
- Subcontractors may be required to report periodically on their compliance program
Examples of Fraud, Waste and Abuse: As described by CMS in the Chapter 9 Guidelines

**Sponsor Level:**
- Failure to provide medically necessary services
- Marketing schemes
- Improper bid submissions (manipulating risk)
- Payments for Excluded Drugs
- Non-compendium payments
- Inappropriate Formulary Decisions (cost over efficacy)
- Inappropriate Enrollment
- False, inaccurate information to CMS
Examples of Fraud, Waste and Abuse: As described by CMS in the Chapter 9 Guidelines

**Sponsor Level continued:**

- Delinquent reimbursement
- Excessive premiums
- Incorrect Calculation of TRooP
- Inaccuracy in Coordination of Benefits
- Bait and Switch Pricing
- Failure to Disclose Rebates, Discounts, or Price Concessions offered by Drug Manufacturer
Examples of Fraud, Waste and Abuse: As described by CMS in the Chapter 9 Guidelines

**PBM Level:**

- Prescription Drug Switching
- Unlawful remunerations for steering benes towards a certain plan or certain drugs
- Inappropriate Formulary Decisions
- Prescription Drug Splitting or Shorting
- Failure to offer negotiated prices
Examples of Fraud, Waste and Abuse: As described by CMS in the Chapter 9 Guidelines

**Pharmacy Level:**
- Inappropriate Billing
- Shorting
- Bait and Switch
- Dispensing counterfeit, adulterated or expired drugs
- TRooP manipulations with patient
- Failure to offer negotiated prices
- Kickback for steering benes to certain drugs or plans
- Script mills, theft of DEA number or prescription pad
Contact Information

**Presenter:** Virginia B. Evans, Esq.
Director, Forensic
Washington, DC
202-533-4433
virginiaevans@kpmg.com