

Compliance, Enforcement, and Discipline

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Introduction to Part D

- Today 24% of Medicare beneficiaries **do not** have prescription drug coverage
- It is estimated that 43 million Medicare beneficiaries will be eligible for Medicare prescription drug coverage in 2006
- By 2030, the number of people Medicare serves will nearly double to 76.8 million

Who Will Be Impacted By Part D?

- Health plans
- Pharmacies
 - Retail
 - Mail
 - Long term care
 - Home infusion, I/T/U
 - 340B
- Pharmacy Benefit Managers
- Providers
- Long-term Care Facilities
- Institutional Pharmacies
- Drug Manufacturers
- Employers

How Are Part D Benefits Offered?

- Stand alone prescription drug plans (PDP)
- MA-PD or PACE-PD
- Cost-based HMOs or Competitive Medical Plans
- Employer plans



Plan Types

- Defined Standard Coverage
- Basic Alternative Coverage
- Enhanced Alternative Coverage


Corporate Compliance Plans for Part D Sponsors

Social Security Act
§ 1806D-4(c)(1)(D):

“The PDP sponsor shall have in place, directly or through appropriate arrangements, with respect to covered Part D drugs ... a program to control fraud, abuse and waste.”

§ 423.504(b)(4)(vi)(H)

A compliance plan must have “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.”



Fraud, Waste and Abuse Program as Part of a Compliance Plan Should Include:

Written policies and procedures and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.

Written Policies and Procedures

Written policies and procedures should include, but not be limited to:

- Code of Conduct that clearly articulates a commitment to comply with all applicable statutory, regulatory and program requirements;
- Policies and procedures to respond to potential violations of Federal and State laws and regulations;

Written policies and procedures (continued)

- Processes for identifying overpayments at any level within its network and the repayment to CMS;
- Policies and procedures for coordinating and cooperating with MEDICs, CMS, and law enforcement; and
- Processes to review the DHHS OIG and GSA exclusion lists for the sponsor's employees and contractors.

Written policies and procedures (continued)

Designation of a compliance officer and compliance committee with responsibility for developing, operating, and monitoring the Fraud and Abuse program and with authority to report directly to the board of directors, the president, or the CEO.

Part D Plan Sponsors must have a compliance officer and compliance committee in place – this function may not be subcontracted.

Written policies and procedures (continued)

Effective training and education between the compliance officer and the organization's employees, contractors, agents and directors on fraud, waste and abuse that would address pertinent laws related to fraud and abuse (for example, anti-kickback provisions and False Claims Act provisions) and common fraudulent schemes in the pharmaceutical industry.

Training and Education

Training and education programs should include:

- A description of the compliance program;
- Review of potential conflicts;
- Review of the disciplinary guidelines for non-compliant behavior; and
- Review of policies related to contracting with the government.

Additionally, employees and contractors should receive specialized training on issues posing compliance risks based on their job functions (e.g., marketing the prescription drug benefit, payment reconciliation, pharmacy claims submission, etc.)

Communication

- Procedures should be in place to protect the anonymity of complainants and protect whistleblowers from retaliation
- Concerns and risks should be reported via independent mechanisms, which may include hotlines, suggestion boxes, employee exit interviews, emails or any other forum that promotes information exchange
- Effective communication can be enhanced by putting in place a complaint tracking system, which includes a call center with an explicit process for handling customer complaints for beneficiaries

Monitoring and Auditing

- Monitoring activities refer to reviews that are repeated regularly during the normal course of operations
- An audit refers to a more formal review of compliance with a particular set of internal or external standards
- Sponsors should develop a monitoring and auditing work plan that addresses risks associated with the Part D benefit

Monitoring and Auditing (continued)

Sponsors should consider methods such as these when developing its policies and procedures for monitoring and auditing to protect against fraud, waste and abuse in Part D:

- Review of high risk areas at the plan level (e.g., enrollment)
- Unannounced internal audits or “spot checks”
- Review of areas previously found non-compliant to determine if the corrective actions taken have fully addressed the underlying problem

Monitoring and Auditing (continued)

- Use of objective, independent auditors that are knowledgeable of the Medicare program requirements and have access to existing audit resources, relevant personnel, and relevant areas of operation; and
- A monitoring and oversight plan that addresses fraud and abuse potentially perpetrated by the pharmacy network, PBM, and all Part D subcontractors



**Fraud, Waste and Abuse Program as
Part of Compliance Plan Should Include:**

Enforcement of standards through guidelines that are widely disseminated to employees, contractors, agents, and directors



**Fraud, Waste and Abuse Program as
Part of Compliance Plan Should Include:**

Procedures to ensure *prompt responses* to detected problems and development of corrective action initiatives

Self-Reporting

- Self-reporting of potential fraud and abuse is a critical element to an effective compliance plan
- Part D Plan Sponsors encouraged to voluntarily self-report potential fraud or misconduct related to the Part D program
- Potential mitigation of damages and/or penalties for Plan Sponsors who report fraud or misconduct to CMS, the MEDICs, or other appropriate government authority

Self-Reporting

- CMS is hiring contractors (MEDICs) to identify, stop, and prevent fraud, waste and abuse in the Part D program
- One MEDIC responsibility is to perform fraud and abuse compliance plan audits in accordance with 42 CFR 423.504(b)(4)(vi)(H)
 - MEDICs will assess Part D sponsors' adherence to CMS' fraud, waste and abuse guidelines
 - MEDICs may perform either onsite reviews or desk audits of Part D sponsor compliance plans

Self-Reporting

- MEDICs will supply CMS with written reports of audit findings, noting deficiencies, recommendations, and best practices
- Based on findings, CMS will follow-up with Part D sponsors as warranted

Enforcement and Discipline

- A communication strategy that results in clear communication of enforcement and disciplinary standards throughout the organization will bolster the effectiveness of a compliance program

Enforcement and Discipline

- Communicating a commitment to compliance is most credible when this commitment clearly states that *all* individuals involved in the work of the organization – regardless of position or status – are accountable for compliance, are subject to the same disciplinary standards, and are expected to fully participate in the compliance effort

Enforcement and Discipline

- Enforcement of standards generally requires establishing an effective working relationship between the compliance program and the functional areas of the organization that have primary responsibility for administering discipline

Enforcement and Discipline

- Oversight by an organization's compliance committee or another appropriate body may bolster effectiveness by enhancing the organization's ability to demonstrate that discipline is proportionate, and is administered fairly and consistently



Enforcement and Discipline

- Does your organization have policies and procedures addressing enforcement of compliance standards and discipline of individuals who violate them?

Enforcement and Discipline

- Does your organization screen employees and business partners before initiating a relationship and periodically, thereafter, to ensure that they have not been excluded by the OIG or GSA?



Enforcement and Discipline

- Is compliance an element of your performance reviews and incentive compensation decisions?



Enforcement and Discipline

- Effective enforcement and discipline requires an investigative process capable of substantiating alleged compliance failures

What to do if the Government is Investigating

- Have attorney contact the government
 - Basis of investigation
 - Issues under investigation
 - Government's theory
- Type of investigation
- Intent to cooperate

Initial Response

- Get counsel
- Stop any questionable conduct
- Preserve documents
- Communicate with and admonish employees
- Initiate internal investigation

What is an Internal Investigation?

- Factual review/legal analysis of potential problems or issues
- Often conducted by:
 - Compliance officers
 - Internal audit departments
 - Outside counsel
 - All of the above
- Usually independent of a government investigation

When is an Internal Investigation Warranted or Necessary?

- Reasonable belief that a problem exists
- Discovery of a potential error
- Actual notice of a potential violation
- Notification from a governmental agency
- Regulatory audit
- Compliance hotline
- Customer, employee, or third-party complaints

Advantages of Conducting an Investigation

- Influence government's investigation
- Interview witnesses
- Identify potential problem areas
- Stop potential violations
- Implement corrective actions



Advantages of Conducting an Investigation

- Document compliance program activities
- Get out of reactive, defensive posture
- Gain superior knowledge
- Help on knowledge and intent issues
- Control internal and external publicity



Attorney vs. Non-Attorney Investigations

- Privilege
- Experts
- Potential for waiver
- Complexity
- Materiality

Whistleblower Protection

- Failure to protect anonymity and confidentiality (don't over-promise confidentiality)
- Failure to prevent retaliation
- The danger of raising employees' expectations and then disappointing them

Discrimination and Disparate Impact

- Imposing compliance discipline consistently
- Conducting background checks and screening new hires
- The difference between arrest records and conviction records

What Factors Determine the Outcome of a Fraud Case?

- Nature of the conduct
- Provider's ability to repay
- Nature of the provider's practice
- First-time offender
- Provider's efforts to correct problem



What Factors Determine the Outcome of a Fraud Case?

- Successor liability
- Period of conduct
- Effectiveness of compliance program
- How matter was discovered
- Level of cooperation

Settlement Factors

- Pre-existing, effective compliance program
- Arose under former management
- Isolated and distinct
- Low-level bad actors

Settlement Factors (continued)

- Dollar amount
- Cooperation and sharing of internal audit
- Candor, flexibility, demonstrated attitude of compliance
- Relationships