

CMS Oversight Strategy for Part D

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Health Care Compliance Association
 April 29, 2009





Session Overview

- **New CMS Compliance/Oversight Structure**
- **Oversight Strategy**
- **Oversight Activities**
- **Alignment of Audit Approach**
- **Statutory & Regulatory Updates**
- **What's on the Horizon?**

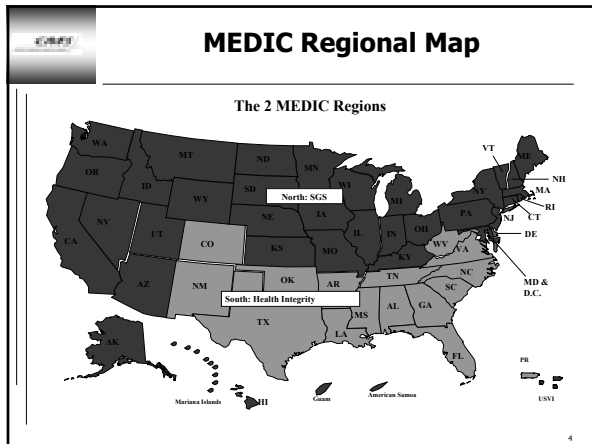
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Medicare Drug Integrity Contractors (MEDICs)

Purpose:
 To ensure the protection of the Medicare Trust Fund and Medicare beneficiaries.

Goal:
 Identify cases of suspected fraud, develop them thoroughly and in a timely manner, and take immediate action to ensure that Medicare Trust Fund monies are not paid inappropriately and that any inappropriate payments are recommended for recoupment.

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- ### Fundamental MEDIC Activities
- Conduct complaint investigations
 - Perform data analysis efficiently and proactively to evaluate inappropriate activity
 - Develop and refer cases to the appropriate law enforcement (LE) agency or take administrative action as appropriate
 - Support ongoing LE investigations
 - Conduct audits
 - Review PDP and MA-PD fraud and abuse compliance programs based on Chapter 9 of the Part D Manual
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- ### PART C OVERSIGHT
- Currently, the MEDICs are only responsible for Part D.
 - Preparations are underway for the MEDICs to oversee Part C plans to identify and prevent cases of suspected fraud.
 - Activities for Part C oversight will be similar to the MEDIC activities for the Part D program.
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CMS PART D OVERSIGHT

The cornerstone of CMS' contractor management activity is analysis of and reaction to Part D program data from contractors, beneficiaries, and the marketplace.

- Many types of self-reported, un-audited data will be submitted by Part D Sponsors. Much of these data will be verified and validated to identify outliers for possible compliance interventions.

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CMS PART D OVERSIGHT

The cornerstone of CMS' contractor management activity is analysis of and reaction to Part D program data from contractors, beneficiaries, and the marketplace.

- Many types of self-reported, un-audited data will be submitted by Part D Sponsors. Much of these data will be verified and validated to identify outliers for possible compliance interventions.
- Program audits are Program Integrity's part of the larger CMS-wide oversight strategy.

CMS Part D Audits

- **There are a variety of audits that CMS can and does perform on Part D Sponsors:**
 - Compliance Plan Audits
 - Benefit Integrity Audits
 - Program Audits
 - Bid Audits
 - Benefit Design Audits
 - One-Third Audits

Compliance Plan Audits

- They are desk audits.
- The Part D sponsor is given 30 calendar days to provide the materials to the MEDIC.
- The MEDIC will provide CMS with the results of the audit.
- Findings from this type of audit could lead to corrective actions and other types of CMS Part D audits.

Compliance Plan Audits

- An effective compliance plan, which must include measures to detect, correct, and prevent fraud, waste, and abuse, must include the following elements:
 - Written Policies and Procedures
 - Compliance Officer and Committee
 - Training and Education
 - Effective Lines of Communication
 - Well Publicized Disciplinary Guidelines
 - Internal Monitoring and Auditing
 - Prompt Response to Detected Offenses and Development of Corrective Actions

Compliance Plan Audits

- The seven elements of the compliance plan can be found at 42 CFR §423.504.
- Chapter 9 provides detailed guidance for a Part D Sponsor (both MA-PD and PDPs) to effectively implement these requirements.

**Part D Compliance Plan Audits –
What is CMS Looking For?**

- **During an audit, Part D sponsors will be expected to demonstrate how they implemented their compliance plan:**
 - to meet the statutory and regulatory requirements; and
 - to identify, prevent and correct fraud, waste and abuse in their operations and the operations of their first tier, downstream, and related entities.

**Part D Compliance Plan Audits –
What is CMS Looking For?**

- **We want to highlight two areas that Part D Sponsors often don't emphasize enough in the development of their compliance plans:**
 - Internal Monitoring and Auditing; and
 - Prompt Responses & Corrective Action Procedures

**Part D Compliance Plan Audits –
What is CMS Looking For?**

- **Internal Monitoring and Auditing**
 - CMS believes that a sponsors' ability to monitor the performance, ensure the effectiveness, and demonstrate oversight of its first tier, downstream, and related entities is an integral part of an effective compliance plan;
 - Sponsors should consider methods such as:
 - Review of high risk areas at the plan level (e.g., enrollment);
 - Unannounced internal audits or "spot checks;" and
 - Review of areas previously found non-compliant to determine if the corrective actions taken have fully addressed the underlying problem.

Part D Compliance Plan Audits – What is CMS Looking For?

- **Prompt Responses & Corrective Action Procedures**
 - Promptly responding to potential offenses should include:
 - ✓ Referral of any abusive or potentially fraudulent conduct or inappropriate utilization activities for further investigation to the MEDICs;
 - ✓ Coordination and cooperation with law enforcement;
 - ✓ Reporting of potential violations of Federal law to the Office of Inspector General (OIG) or other appropriate law enforcement authorities;
 - ✓ The role and responsibilities of Special Investigations Units if applicable; and
 - ✓ The development of appropriate corrective actions, including the repayment of any overpayments.

Part D Compliance Plan Audits – What is CMS Looking For?

- **Helpful Tips:**
 - Make sure there is a Compliance Officer or a Compliance Committee;
 - Ensure there is documented evidence of compliance training, including training provided to first tier, downstream, and related entities; and
 - Provide evidence that the Compliance Committee functions are not delegated to a subcontractor

Benefit Integrity Audits

- **Benefit Integrity Audits are conducted by the MEDICs and are conducted on an *ad hoc* basis.**
- **A benefit integrity audit, also called a targeted audit, is performed if there is a concern that the repeated or related activities of a Part D Sponsor surrounding a particular issue could put the agency and/or a beneficiary at risk.**
- **With a benefit integrity audit, the MEDICs will audit a Part D Sponsor based on data that suggests aberrant behavior on the part of a Part D Sponsor providing the benefit, as well as a beneficiary utilizing the benefit.**

Program Audits

- **Conducted by CMS Regional Offices**
- **Helps CMS ascertain if Part D Sponsors are in compliance with all guidance and regulations associated with providing the Part D benefit.**
- **Areas that can be included in a program audit are:**
 - Enrollment and Disenrollment
 - Marketing
 - Grievances
 - Licensure & Solvency
 - Access
- **These audits are a combination of desk and on-site activities.**

CMS Part D Audits

- **Though CMS does not have a statutory requirement for how often the compliance plan, benefit integrity or program audits should be conducted, CMS recommends that Part D Sponsors stay on alert and be prepared.**

One-Third Audits

- **CMS annually audits 1/3 of the MAOs offering MA-Plans and 1/3 of the Part D drug plans.**
- **Applicable Part D Regulations (42 CFR 423.504 (d)):**
Protection against fraud and beneficiary protections. (1)
CMS annually audits the financial records (including, but not limited to, data relating to Medicare utilization and costs, including allowable reinsurance and risk corridor costs as well as low income subsidies and other costs) under this part of at least one-third of the part D drug plans.
- **Audits are conducted by the Office of Financial Management**

**One Third Audits –
What is CMS Looking For?**

Part D Audit Elements include the following items:

- Part D Costs and Payments
- Direct and Indirect Remuneration (DIR)
- True Out of Pocket Costs (TrOOP)
- Sponsors' Solvency
- Sponsors' Related Party Transactions and Administrative Costs

How are these audits coordinated?

- All of these different types of audits are currently underway
- With the exception of benefit integrity audits, each type of audit is typically looking at different areas of the Part D program.
- CMS is in the process of redefining our approach to oversight activities to minimize duplicative efforts while ensuring the Agency meets it's obligation to provide appropriate contractor oversight.
- However, CMS has no control of audit or information requests from other government entities, e.g. OIG.
- CMS acknowledges that audits are time consuming, and we will continue to coordinate these audits as much as possible.

MEDICS AND ZPICS

- CMS has begun implementing its strategy to align the existing Program Safeguard Contracts geographically with the Medicare Administrative Contracts (MAC).
- Under this new strategy CMS will divide the nation into seven zones, each of which contains one or more entire MAC jurisdictions. Each zone will have a Zone Program Integrity Contractor (ZPIC) that performs benefit integrity functions.

MEDICS AND ZPICS

Part D sponsors should be aware that the MEDICs continue to function as the Program Safeguard Contractor for Part D.

Sponsors will be notified of any transition to new contractors.

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Questions

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