

# Fraud and Abuse Oversight Strategy for Part C and Part D



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## Program Integrity and Part D


- I. Program Integrity Fraud and Abuse Oversight Strategy**
- II. Definition and Functions of MEDICs**
- III. Program Integrity Audits**
- IV. MEDICs and ZPICs**
- V. Compliance Effectiveness Pilot**
- VI. Summary**

 <small>CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</small>	<h2>Program Integrity's Fraud and Abuse Oversight Strategy</h2>
	<ul style="list-style-type: none"><li>• <b>Coordinated approach to oversight:</b><ul style="list-style-type: none"><li>– Compliance Plan and Benefit Integrity Audits</li><li>– Data analysis</li><li>– Referral of complaints</li><li>– Beneficiary education re: potential fraud</li></ul></li></ul>

 <small>CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</small>	<h2>Centralized PI Activities</h2>
	<ul style="list-style-type: none"><li>• <b>Focus on Data Analysis:</b><ul style="list-style-type: none"><li>– Identify potential fraud, waste and abuse in Parts C and D</li><li>– Routine Reports and Evaluations</li></ul></li><li>• <b>Focus on fraud, waste and abuse:</b><ul style="list-style-type: none"><li>– Coordinate efforts across CMS, contractors and law enforcement</li><li>– Issue fraud alerts</li><li>– Prepare fraud and abuse materials for the press and beneficiary outreach efforts</li></ul></li></ul>

 <small>CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</small>	<h2>On the Ground Monitoring</h2>
	<ul style="list-style-type: none"><li>• <b>Perform data analysis</b></li><li>• <b>Investigate possible fraud:</b><ul style="list-style-type: none"><li>– fraudulent enrollments</li><li>– improper eligibility determinations</li><li>– payment scams</li><li>– fraud complaints from Plans, CMS and/or beneficiaries</li><li>– conduct compliance and benefit integrity audits</li></ul></li><li>• <b>Develop and refer cases to law enforcement</b></li></ul>

 <small>CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</small>	<h2>Law Enforcement Partnership</h2>
	<ul style="list-style-type: none"><li>• <b>Program Integrity will coordinate with Law Enforcement:</b><ul style="list-style-type: none"><li>– Designated a Program Integrity Law Enforcement Liaison</li><li>– Collaborate with law enforcement on the development of Part D policy, initiatives, regulations and instructions relating to law enforcement</li><li>– Educate OIG agents, AUSA, and FBI on the Part D benefit</li></ul></li></ul>




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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.

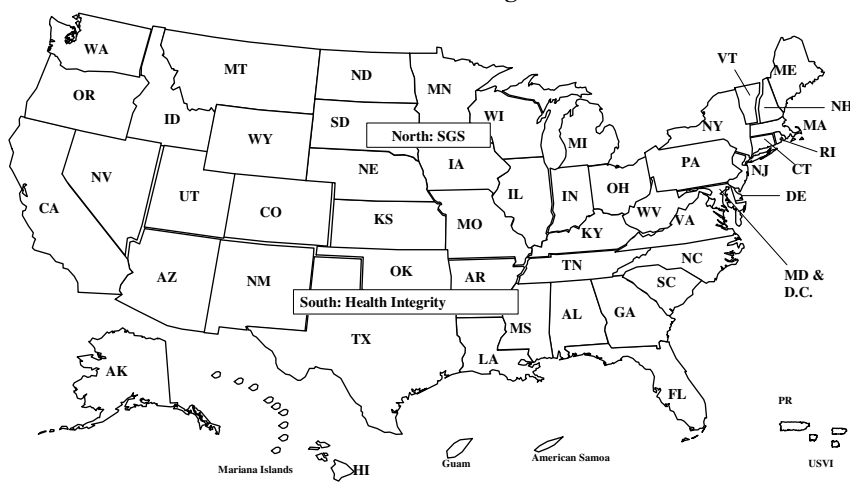
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## MEDIC Regional Map


**The 2 MEDIC Regions**





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	<h2>MEDIC Contact Information</h2>
<p><b><u>MEDIC North: Electronic Data Systems (EDS) Corporation</u></b> By phone: 877-7SAFERX (877-772-3379) By fax: 717-975-4442 *In writing: MEDIC North 225 Grandview Avenue, Mail-stop F10 Camp Hill, PA 17011</p> <p><b><u>MEDIC South: Delmarva/Health Integrity</u></b> By phone: 877-7SAFERX (877-772-3379) By fax: 410-819-8698 *In writing: Health Integrity Attention: MEDIC 9240 Centreville Road Easton, MD 21601</p> <p style="text-align: right;">*Note: Both Regional MEDICs can be reached by the same number: 1-877-772-3379</p>	


	<h2>Fundamental MEDIC Activities</h2>
<ul style="list-style-type: none"><li>• Conduct complaint investigations</li><li>• Perform data analysis efficiently and proactively to evaluate inappropriate activity</li><li>• Develop and refer cases to the appropriate law enforcement (LE) agency or take administrative action as appropriate</li><li>• Support ongoing LE investigations</li><li>• Conduct compliance plan and benefit integrity audits</li><li>• Review PDP and MA-PD fraud and abuse compliance programs based on Chapter 9 of the Part D Manual</li></ul>	


	<h2>Coordination and Education Requirements</h2>
<p>MEDICs must coordinate with other entities to ensure efforts are coordinated to stop fraud.</p> <ul style="list-style-type: none"> <li>• <b>Part C Organizations</b></li> <li>• <b>Part D Sponsors</b></li> <li>• <b>Other Medicare Contractors (FI, Carriers, etc...)</b></li> <li>• <b>OIG</b></li> <li>• <b>DOJ</b></li> <li>• <b>FBI</b></li> <li>• <b>State Agencies (MFCU, etc...)</b></li> <li>• <b>Law Enforcement Task Forces</b></li> <li>• <b>Quality Improvement Organizations</b></li> <li>• <b>Private Health Insurers</b></li> <li>• <b>Other Specialty Contractors</b></li> <li>• <b>Other Federal and State Agencies</b></li> </ul>	


	<h2>Chapter 9 - Part D Program to Control Fraud, Waste and Abuse</h2>
<p><b><u>Purpose:</u></b></p> <p>To provide guidance on how to implement a comprehensive program to prevent and detect fraud, waste and abuse based on the statutory and regulatory requirements.</p> <p>CMS is in the process of revising Chapter 9 of the Prescription Drug Benefit Manual to comply with the final regulation published December 5, 2007.</p> <p>Until separate guidance on fraud, waste, and abuse is specifically designed for Part C organizations, they should refer to Chapter 9.</p>	

 <small>CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</small>	<h2>CMS Fraud and Abuse Audits</h2>
<ul style="list-style-type: none"><li>• <b>Program Integrity can and does perform:</b><ul style="list-style-type: none"><li>– Compliance Plan Audits</li><li>– Benefit Integrity Audits</li></ul></li></ul>	
<p style="text-align: right;">13</p>	

 <small>CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</small>	<h2>Compliance Plan Audits</h2>
<ul style="list-style-type: none"><li><b>I. Who is conducting compliance plan audits?</b><ul style="list-style-type: none"><li>• The MEDICs – Health Integrity, LLC &amp; SGS</li></ul></li><li><b>II. When did the compliance plan audits start?</b><ul style="list-style-type: none"><li>• The 1<sup>st</sup> engagement letters were sent on 10/3/2008</li></ul></li><li><b>III. What tools are the auditors using to conduct the compliance plan audits?</b><ul style="list-style-type: none"><li>• Chapter 10 of the CMS Audit Guide</li></ul></li></ul>	
<p style="text-align: right;">14</p>	


 <p>CMS CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</p>	<h2>What Are the Compliance Plan Audits?</h2>
<ul style="list-style-type: none"><li>– They are desk audits.</li><li>– The plan is given 30 calendar days to provide the materials to the MEDIC.</li><li>– The MEDIC will provide CMS with the results of the audit.</li><li>– Findings from this type of audit could lead to corrective actions and other types of audits.</li></ul> <p style="text-align: right;">15</p>	

 <p>CMS CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</p>	<h2>Compliance Plan Audits</h2>
<ul style="list-style-type: none"><li>• <b>Plans are required to have and implement an effective compliance plan as a condition of participation in the Medicare program.</b></li><li>• <b>During a compliance plan audit, plans will be expected to demonstrate how they implemented their compliance plan to not only meet the statutory and regulatory requirements but also to identify, prevent and correct fraud, waste and abuse in their operations and the operations of their first tier, downstream, and related entities.</b></li></ul> <p style="text-align: right;">16</p>	

 **Compliance Plan Audits**


- **The seven elements of an effective compliance plan are:**
  - 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
- **These can be found at 42 CFR section 423.504.**


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 **How Were Sponsors Selected?**

- The MEDICs identified six main complaint categories for analysis:
  - **Quality of Care**
    - Prescription Shortages
    - Formulary Issues
  - **Cost/Payment**
    - Pharmacy Billing Practices
    - TrOOP Miscalculation Issues
  - **Enrollment**
    - Inappropriate Enrollment In a MA-PD
    - Door-to-Door Marketing
  - **Marketing Complaints**
    - Deceptive Activities Involving Agents
  - **EOB Complaints**
    - Incorrect Prescription Information
    - Incorrect Beneficiary Information
  - **Drug Diversion**
    - Falsification of Information by Prescriber
    - Beneficiary Prescription Diversion

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 <p>CMS CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</p>	<h2>How Were Sponsors Selected?</h2>
<ul style="list-style-type: none"><li>• The MEDICs queried their internal databases, to identify Sponsors that had complaints in the designated categories.</li><li>• From that list the MEDICs organized the Sponsors based upon risk to the program.</li></ul>	
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 <p>CMS CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</p>	<h2>Preliminary Findings</h2>
<ul style="list-style-type: none"><li>• <b>The auditors found that the Sponsors were compliant with most of the program requirements</b></li><li>• <b>There were elements where some Sponsors were non-compliant. Some findings include:</b><ul style="list-style-type: none"><li>– No Compliance Officer or Compliance Committee</li><li>– No evidence of compliance training</li><li>– No published disciplinary guidelines</li><li>– No evidence that the Compliance Committee functions were not delegated to a sub-contractor</li></ul></li></ul>	
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## Compliance Plan Audits

- **Though Program Integrity does not have a statutory requirement for how often the compliance plan audits should be conducted, CMS recommends that plans stay on alert and be prepared.**
- **The findings of the compliance plan audits may be used to assist CMS in developing additional guidance for Chapter 9.**

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## 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 Part C and D plans 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 C or D plan based on data that suggests aberrant behavior on the part of a Part C or D plan providing the benefit, as well as a beneficiary utilizing the benefit.**

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## 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.
- 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.


## Compliance Effectiveness Pilot


**The CMS Compliance Effectiveness Pilot had two primary purposes:**


- 1. Identify metrics that would assist CMS and the provider community in determining whether their compliance plans are “effective”; and**
- 2. Explore how elements of a compliance plan impact the accuracy of Medicare billing and claims submission.**


 <p>CMS CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</p>	<h2>Preliminary Site Visit Observations</h2>
	<ul style="list-style-type: none"><li>• Importance of buy-in to the compliance program by senior leadership at hospital;</li><li>• Importance of the compliance officer;</li><li>• Importance of relationships a compliance officer has across multiple departments (including board members and CEO);</li><li>• Methods in which electronic data is utilized and the importance of human oversight in that process;</li><li>• Importance of an integrated auditing approach; and</li><li>• Importance of the coding process and patient registration/access systems in billing compliance</li></ul> <p>25</p>


 <p>CMS CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</p>	<h2>Survey Result Observations</h2>
	<ul style="list-style-type: none"><li>• <b>Standards and procedures were documented in various forms and approved by Senior Management (Board)</b></li><li>• <b>Accountability of the compliance program existed at a senior level and usually included Board involvement</b></li><li>• <b>Education and training occurred on a regular basis to employees <u>and</u> medical staff. Many also included vendors, contractors and volunteers</b></li></ul> <p>26</p>


 <small>CENTRE ON MEDICAL &amp; MEDICAL SERVICES</small>	<h2 style="text-align: center;">Survey Result Observations</h2>
<ul style="list-style-type: none"><li>• <b>Education and training materials were almost uniformly updated at least annually and the method of training varied widely</b></li><li>• <b>Appropriate lines of communication were in place to include regular reports to the Board on compliance issues</b></li><li>• <b>Communication included regularly disseminating key information to staff on an ongoing basis regarding compliance issues</b></li></ul>	
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 <small>CENTRE ON MEDICAL &amp; MEDICAL SERVICES</small>	<h2 style="text-align: center;">Survey Result Observations</h2>
<ul style="list-style-type: none"><li>• <b>Auditing almost always included an internal and external component, with the majority of entities primarily doing most of their auditing internally with external auditors being used to verify those findings</b></li><li>• <b>Coordination of audit results varied widely across participants</b></li><li>• <b>Corrective actions were usually handled using a progressive disciplinary process</b></li></ul>	
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 <small>CENTER FOR MEDICARE &amp; MEDICAID SERVICES</small>	<h2 style="text-align: center;">Key Findings of Pilot</h2>
	<ul style="list-style-type: none"><li>• <b>The Pilot Determined that compliance programs are a worthwhile financial investment</b><ul style="list-style-type: none"><li>– Participants had significant changes in their outcome variables (claims data) as a result of their compliance programs.</li><li>– Having appropriate staff to coordinate and oversee compliance and billing efforts helps prevent duplication of efforts across organization and can have a positive result on resources (both financially and human resources)</li></ul></li></ul>

 <small>CENTER FOR MEDICARE &amp; MEDICAID SERVICES</small>	<h2 style="text-align: center;">Key Findings of Pilot</h2>
	<ul style="list-style-type: none"><li>• <b>Many of the Preliminary Site Visit Observations were confirmed as essential to overall effectiveness of the compliance program</b><ul style="list-style-type: none"><li>– Senior leadership support of and buy-in to compliance program efforts are critical</li><li>– Compliance officer role (both perceived and actual) is also essential</li><li>– Importance of relationships throughout the organization</li><li>– Importance of proper use of data</li><li>– Importance of effective auditing techniques</li></ul></li></ul>


 <small>CENTER FOR MEDICARE &amp; MEDICAID SERVICES</small>	<h2 style="text-align: center;">Key Findings of Pilot</h2>
	<ul style="list-style-type: none"><li>• <b>The Seven Elements of a compliance program are important individually, but are most effective on an interdependent basis</b><ul style="list-style-type: none"><li>– Lines of communication correlated very closely with education and training as well as audit and monitoring</li><li>– Standards and procedures correlated very closely with enforcement and discipline</li></ul></li></ul>

 <small>CENTER FOR MEDICARE &amp; MEDICAID SERVICES</small>	<h2 style="text-align: center;">Key Findings of Pilot</h2>
	<ul style="list-style-type: none"><li>• <b>Compliance Programs are indeed effective and needed by organizations</b><ul style="list-style-type: none"><li>– This was evidenced by the quantitative, qualitative and anecdotal data from the pilot participants</li></ul></li></ul>

 **Qualitative Data Key Findings**


- **Code of Conduct CMS recommendations:**
  - Issue under the signature of the CEO of the hospital
  - Make sure it is short, plainly worded and is a separate document apart from policies and procedures
  - Provide to all employees upon initial orientation and during annual compliance training
  - Distribute to all employees, physicians and Board
  - Require employees to sign that they have received
  - Post prominently (poster and/or intranet)


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 **Qualitative Data Key Findings**

- **Policies and Procedures:**
  - Maintain separate from the Code of Conduct
  - Clearly written and well-defined policies and procedures directed at all staff are most effective
  - Must be approved by Senior management, if not the Board.
  - Have a periodic and regularized review of the policies
  - Use template to track policy changes and approvals such as
    - Issue Date
    - Last Revision Date
    - Last Review Date
    - Last Author
    - Approved By
    - Document Location

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 <p><b>CMS</b> CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</p>	<h2>Qualitative Data Key Findings</h2>
<ul style="list-style-type: none"><li>• <b>Education and Training:</b><ul style="list-style-type: none"><li>– Methods vary widely across pilot participants</li><li>– Key element to success was involvement of compliance officer in developing training</li><li>– In person training was most effective for physicians</li><li>– Annual compliance training was essential to reinforcing importance of compliance program</li><li>– Critical to coordinate training focus with key risk areas identified within organization</li></ul></li></ul>	
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 <p><b>CMS</b> CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</p>	<h2>Qualitative Data Key Findings</h2>
<ul style="list-style-type: none"><li>• <b>Lines of Communication:</b><ul style="list-style-type: none"><li>– Electronic tracking of complaints received is essential to ensure appropriate follow up</li><li>– Regular reports of complaints should be generated and provided to senior leadership</li><li>– Reporting to Board should not just be statistics, but give flavor of nature and type of complaints</li><li>– Compliance officers who used multiple methods of communication seemed to yield the best results</li><li>– Employee exit interviews are very effective in identifying areas for improvement</li></ul></li></ul>	
<p style="text-align: right;">36</p>	

## Qualitative Data Key Findings

- **Audit and Monitoring:**
  - Communication is essential to ensure coordination of efforts and avoid duplication. Many hospitals do not share results across organization and this is counter productive.
  - Development of an audit plan is critical. This can include frequency and timing of audits, timing of reporting, staffing needs, etc. These should be adjusted annually and updated on an ongoing basis.

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## Summary and Next Steps

- **Implications of the Compliance Effectiveness Pilot for Managed Care Organizations**
  - Strategies and techniques for developing an effective compliance plan
  - Information on avoiding the pitfalls made by these providers
  - Executive Summary document being created to identify best practices that will be applicable to all provider types

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# Questions

## Contact Information

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