

# CMS Mandatory Compliance Plans: What You Need to Know!

**Friday, February 11, 2011 - 12:00-1:00 pm Eastern**

*This brown bag is brought to you by the Payors, Payment, and Managed Care (PPMC) Practice Group*

Presenters:

**Brenda Tranchida, JD**

Director of the CMS Program Compliance and Oversight Group

**Marianne Bechtle, JD**

Health Insurance Specialist for the  
CMS Program Compliance and Oversight Group

*We would like to thank MA and Part D Affinity Group Co-Chairs Janice Ziegler, Esquire (SNR Denton, Washington, DC), and Lyn Amor Macaraeg, Esquire (CareMore Health Plan, Cerritos, CA), for planning this call*

# **WELCOME TO THE MA & PART D AFFINITY GROUP**

## **Mission Statement**

**The MA & Part D Affinity Group seeks to serve as a lively platform for active discussion and interaction between PPMC PG members who represent entities involved in the MA and Part D programs.**

# MA & PART D AFFINITY GROUP OBJECTIVES

- **Forum for Focused Exchange on MA and Part D Matters**
- **Networking**
- **Programming**
- **Member Involvement**

# INTERESTED IN VOLUNTEERING?

- Help with brown bag luncheon programs;
- Author MA and/or Part D-focused articles for the AHLA newsletter or white papers;
- Aid in recruitment of other volunteers;
- Speak at a webinar or brown bag luncheon on a topic of interest to the MA & Part D Affinity Group.

# JOIN THE MA & PART D AFFINITY GROUP

- Send an email indicating your interest in the MA & Part D Affinity Group to:

**[pgs@healthlawyers.org](mailto:pgs@healthlawyers.org)**

- Note: Must be a PPMC Member

# OUR SPEAKERS



## **Brenda Tranchida, JD**

- Member of the Senior Executive Service and Director of the Program Compliance and Oversight Group within the Center for Medicare at CMS.

# OUR SPEAKERS



## **Marianne Bechtle, JD**

- Health Insurance Specialist in the Division of Compliance and Enforcement within the Program Compliance and Oversight Group at the CMS.

# CMS Mandatory Compliance Plans: What You Need to Know!

Brenda Tranchida, JD, Director  
Marianne Bechtle, JD, Health Insurance Specialist  
Program Compliance and Oversight Group  
Center For Medicare  
February 11, 2011

American Health Lawyers Association  
Medicare Advantage and Part D Affinity Group  
Brown Bag Webinar

# Today's presentation

- 2010 Enforcement Update
- 2010 On-Site Audits Update
- Compliance Plan Requirements and Audits
- Compliance Plan Effectiveness
- Compliance Officer and Organizational Best Practices

# 2010 Contract Sanctions/Terminations

Type of Action	Contracts Affected	Violations	Immediate? (evidence of imminent & serious risk)
Marketing and Enrollment Sanction	PDP	Formulary Administration (Transition, UM, Protected Class Drugs), Coverage Determinations and Appeals	Yes
Termination	PDP	Formulary Administration (Transition, UM, Protected Class Drugs), Coverage Determinations and Appeals, Compliance Plan	Yes
Marketing and Enrollment Sanction	PDPs and MA-PDs	Formulary Administration (Transition, UM,), Coverage Determinations and Appeals; LIS Best Available Evidence	No
Marketing and Enrollment Sanction	PDPs and MA-PDs	Formulary Administration (Transition, UM, Protected Class Drugs), Oversight of Delegated Entities (PBM), Coverage Determinations and Appeals, Grievances, Premium Billing, Waiver of Liability for MA Appeals, Compliance Plan	No
Marketing and Enrollment Sanction	PDPs and MA-PDs	Formulary Administration (Transition, UM, Protected Class Drugs), Coverage Determinations and Appeals, Compliance Plan	Yes
Marketing and Enrollment Sanction	MA-PDs	Agent/Broker Marketing, Compliance Plan	No
Marketing and Enrollment Sanction	MA-PDs	Agent/Broker Marketing, Compliance Plan	No

# 2010 Civil Money Penalties

Number of CMPs Issued	Violations Cited	Penalty Amounts By Violation
1	Late Beneficiary Communications (2010 Annual Notice of Change/Evidence of Coverage (ANOCs/EOCs))	\$ 57,240
7	Inaccurate Beneficiary Communications (2010 ANOCs/EOCs)*	\$200,930
1	Failure to Timely Bill Premiums	\$509,000
<b>Total :</b>		<b>Total :</b>
9	* Note: In January 2011, an additional CMP (\$171,240) was issued for inaccurate 2010 ANOCs/EOCs; therefore, the total CMPs for these kinds of 2010 violations = \$372,170	\$767,170

# 2010 Enforcement Actions

All enforcement letters posted and publicly available on CMS website

<http://www.cms.gov/MCRAdvPartDEnrolData/EA/list.asp#TopOfPage>

# 2010 On-Site Audits

- Background:
  - Parent organization level
  - Selection based on risk assessment
  - Quality assurance and quality improvement goals
- Numbers:
  - 33 on-site audits
  - 11 compliance plan-only audits
    - Re-audits or other bases for compliance plan only audits
    - Reports issued January 2011
  - 22 performance + compliance plan audits
    - Reports pending
- 2010 Enforcement Actions Utilized Audit Results:
  - 1 Termination
  - 5 Marketing/Enrollment Sanctions
  - Ineffective compliance program at all sanctioned organizations

# 2010 On-Site Audits

- Audit Review Areas:
  - ✓ Formulary Administration (Transition, Utilization Management (UM), Protected Class Drugs)
  - ✓ Prescription Drug Coverage Determinations, Appeals, Grievances
  - ✓ Premium Billing
  - ✓ Enrollment/Disenrollment
  - ✓ Compliance Plan (always audited along with other programmatic areas)

# 2010 On-Site Audits

- Process:
  - “C- level” (CEO, COO, CFO) engagement during audit process
  - Use of probe via data samples (e.g., rejected pharmacy claims)
  - Further data requests on-site (e.g., when serious problems detected or to determine scope of beneficiaries affected)
  - Immediate corrective action for any access issues detected

# 2010 On-Site Audits

- Corrective Action Process:
  - 60 calendar days to correct from date of report
  - Attestation from CEO:
    - All audit report deficiencies corrected and not likely to recur; and
    - Compliance program modified to correct all deficiencies and complies with all CMS requirements
  - Board of Directors adopted resolution (at least quarterly meetings to conduct review and oversight of Medicare compliance obligations/operations)
  - Validation requires evidence of correction (e.g., review of period of rejected pharmacy claims)
- Transparency:
  - Audit results posted on CMS web

# 2010 On-Site Audits

- Process Improvements:
  - Listening sessions held with industry associations and sponsors (AHIP and Blues)
    - More advance notice and response time
    - More transparency and information re: expectations
    - Easier electronic exchange of information
    - Availability of Audit guides
    - Ability to respond/dispute
  - 2011 audit planning in process
  - Use of self-assessment evaluation tools

# Compliance Plan Requirements

- Final Regulations - 75 Fed. Reg. 19678 (April 15, 2010)
  - 422 CFR 503(b)(4)(vi), 423 CFR 504(b)(4)(vi)
  - Compliance program changes became effective 1/1/2011
- Updates specifically require a compliance “program” (vs. “plan”) to be “effective”
- Updates provide more detailed regulatory requirements on each of the 7 compliance program elements

# Compliance Plan Requirements

- Among other important new requirements, new regulations explicitly require sponsors to:
  - “Adopt and implement”
  - “an *effective* compliance program”
  - “which must include measures that prevent, detect, and correct non-compliance with CMS’ program requirements”
  - “as well as measures that prevent, detect, and correct fraud, waste, and abuse”
  - “must, *at a minimum*, include” the 7 core element requirements listed in the regulation

[emphasis added]

# Compliance Plan Requirements

Elements	2010 Regulations	2011 Regulations
I – P & Ps and standards of conduct	Articulate commitment to comply with laws	<ul style="list-style-type: none"> <li>•Describe compliance expectations</li> <li>•Implement compliance operations</li> <li>•Provide guidance to employees and others</li> <li>•Identify how to communicate issues</li> <li>•Describe investigation and resolution process</li> <li>•Include non-intimidation policy</li> </ul>
II – Compliance Officer and Committee	CO and CC accountable to senior management	<ul style="list-style-type: none"> <li>•CO and CC report directly and accountable to CEO/other senior management</li> <li>•CO employee of sponsor, parent or affiliate; <u>not</u> employee of FDR</li> <li>•CO and CC report directly to Board on compliance program, issues, investigations and resolutions</li> <li>•Board knowledgeable on content and operations and exercises reasonable oversight of implementation and effectiveness of compliance program</li> </ul>

# Compliance Plan Requirements

Elements	2010 Regulations	2011 Regulations
III – Training & Education	Effective T&E between CO and sponsor’s employees, managers, directors and FDRs	<ul style="list-style-type: none"> <li>•Establish, implement and provide</li> <li>•CEO, senior administrators/ managers, and Board members</li> <li>•At least annually and part of orientation for new employees, CEO, senior administrator/managers, Board and FDRs</li> <li>•T&amp;E FWA requirement deemed to be met for providers/suppliers and DME/POS that have been FWA certified through Medicare FFS enrollment/accreditation process</li> </ul>
IV – Effective Lines of Communication	Effective lines of communication between CO/CC and sponsor’s employees, managers, directors and FDRs	<ul style="list-style-type: none"> <li>•Establish and Implement</li> <li>•Ensures confidentiality</li> <li>•Board included in CO/CC lines of communications</li> <li>•Accessible to all</li> <li>•Allow issues to be reported</li> <li>•Includes anonymous and confidential good faith reporting method</li> </ul>

# Compliance Plan Requirements

Elements	2010 Regulations	2011 Regulations
V – Disciplinary Standards	Enforcement of standards through well publicized disciplinary guidelines	<ul style="list-style-type: none"> <li>•Implementation of procedures which encourage good faith participation by all</li> </ul> <p><u>Standards include:</u></p> <ul style="list-style-type: none"> <li>•Expectations for reporting and assisting in resolution</li> <li>•Identification of non-compliant/unethical behavior</li> <li>•Timely, consistent, effective enforcement of standards</li> </ul>
VI – Monitoring and Auditing	Procedures for effective internal monitoring and auditing	<ul style="list-style-type: none"> <li>•Establish and implement effective system for routine monitoring and identification of risks</li> <li>•System includes internal monitoring and audits to evaluate sponsors' and FDRs' compliance with CMS requirements</li> <li>•System to evaluate overall effectiveness of compliance program</li> <li>•External audits, as appropriate</li> </ul>

# Compliance Plan Requirements

Elements	2010 Regulations	2011 Regulations
VII - Prompt Response to Detected Offenses	<ul style="list-style-type: none"> <li>•Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives</li> <li>•If evidence of misconduct related to payment or delivery of items or services, must conduct timely, reasonable inquiry into conduct</li> <li>•Must conduct appropriate corrective action (repayment and discipline) in response to violation</li> <li>•Should have voluntary self-reporting procedures to CMS/designee for fraud/misconduct</li> </ul>	<ul style="list-style-type: none"> <li>•Establish and implement procedures and a system for prompt response to issues</li> </ul> <p><u>Procedures and a system to:</u></p> <ul style="list-style-type: none"> <li>•Investigate potential problems identified through self-evaluation and audit</li> <li>•Promptly and thoroughly correct problems to reduce recurrence potential and ensure on-going compliance</li> </ul>

# Compliance Plan Audits

- On-site
- Not just a “paper exercise” (“print, post and pray”)
- Validation activities (data, personnel, documentation)
- Evaluating effectiveness – (e.g., can you show you have a systemic process for proactively finding and fixing non-compliance and FWA issues?)
- Includes focus on requirements to implement programs to control and combat fraud, waste and abuse (FWA)

# Compliance Plan Audits - Key Deficiency Findings

- CCO has indirect or infrequent reporting relationship to CEO/Board
- CCO has direct reporting relationship to legal counsel or performs dual roles (conflict of interest)
- Lack of sufficient “C” level/Board level involvement, awareness, oversight and support of compliance functions

# Compliance Plan Audits - Key Deficiency Findings

- Lack of senior management involvement in, review and endorsement of standards of conduct and compliance/FWA policies and procedures
- Failure to ensure receipt of comprehensive, up to date, policies and procedures and standards of conduct (including to FDRs) and/or to implement mechanisms for ensuring adherence to them (e.g., reporting mechanisms, non-retaliation, disciplinary guidelines for failing to report, etc.)

# Compliance Plan Audits – Key Deficiency Findings

- Lack of awareness of confidential, anonymous reporting mechanisms (including by FDRs, beneficiaries, etc.)
- Compliance and/or FWA training not up to date and targeted to individual job duties/risks and not tracked and/or measured to determine whether timely received/effective

# Compliance Plan Audits

## Key Deficiency Findings

- Lack of organizational compliance and FWA risk assessments
- Major functions are delegated to outside entities (e.g., PBMs) without exercising proper monitoring, oversight and auditing to ensure compliance/detect FWA

# Compliance Plan Audits – Key Deficiency Findings

- Failure to implement systems for tracking and ensuring prompt response to detected non-compliance and FWA
- Applying compliance models/processes that do not meet Medicare requirements (e.g., using commercial business compliance models)

# Compliance Plan Audits

## Key Deficiency Findings

- Failure to implement and oversee OIG provider exclusion and GSA debarment lists processes to screen out providers/suppliers
- Lack of specific mechanisms targeted to FWA (e.g., monitoring/auditing in high fraud geographic areas, provider types, operations, etc.)
- Failure to report FWA to CMS MEDIC

# Compliance Plan Effectiveness

- Affordable Care Act Sections 6401/6102: expanded mandatory compliance programs to rest of Medicare program (FFS providers/suppliers) and to the Medicaid (providers/suppliers, nursing facilities/skilled nursing facilities) and CHIP programs.
- States also requiring effective compliance programs as condition of participation – e.g., New York Medicaid program

# Compliance Plan Effectiveness

- Key business operations managers accountable for compliance, not CCO.
- Governing body and “C” level execs engaged (LEADERSHIP!)
- Structure, process and outcomes approach for effectiveness
- Use of metrics (“scorecard”) of some sort to assure measurement occurs and focus on improvement
- Example – use of a point system
  - Points added for implementing structures (7 required elements), oversight processes and achieving positive outcomes.
  - Points deducted for lack of structure, processes, regulatory notices, fines, sanctions.

# Compliance Plan Effectiveness

Indicators that you do not have an effective program:

- CO does not report to the Board/chief executive
- No Compliance Committee
- No confidential / anonymous reporting
- Employees afraid to report up their chain
- Disregards monitoring data; no or infrequent audits
- Responds to incident but no systemic fix
- No or negative recognition for compliance reports, complaints
- Discipline inadequate / inconsistent
- Allegations not effectively investigated
- No systematic efforts to build a strong ethical culture

# Compliance Plan Effectiveness Self Assessment Tool

- Working draft
- Framework for assessing strengths and weaknesses against CMS requirements
- Share responses with senior management and Board to focus on compliance program
- CMS considering using tool prior to audit to gather information and aid audit efforts
- Modeled after self-assessment tools developed by New York State Office of Medicaid Inspector General (OMIG) and HCCA

Sources:

[http://www.omig.ny.gov/data/images/stories/compliance\\_alerts/2010-02.pdf](http://www.omig.ny.gov/data/images/stories/compliance_alerts/2010-02.pdf)

<http://www.hcca-info.org/Content/NavigationMenu/ComplianceResources/ComplianceBasics/CompEvalCheckList.pdf>

# Compliance Plan Effectiveness Self Assessment Tool

<b>ELEMENT I: Written Policies and Procedures and Standards of Conduct</b>			
<b>Description</b>	<b>Yes</b>	<b>No</b>	<b>Evidence of Compliance or Action Required</b>
Have you performed a risk assessment of your Medicare business operational and legal risks and have your risk areas been prioritized and resources allocated accordingly?			
Does the risk assessment include an evaluation of Medicare Parts C & D program requirements, as well as risk areas identified in publications such as the HPMS Memos, OIG Work Plans, Fraud Alerts, Guidances for MA plans and PDP plans and Special Advisory Bulletins?			

# Compliance Plan Effectiveness Self Assessment Tool

<b>ELEMENT I: Written Policies and Procedures and Standards of Conduct</b>			
<b>Description</b>	<b>Yes</b>	<b>No</b>	<b>Evidence of Compliance or Action Required</b>
Are your P & Ps specific and detailed in describing the mechanisms by which compliance objectives will be achieved?			
Do your P & Ps cover all major risk areas?			
Has your compliance program been implemented?			
Do you perform <u>proactive</u> oversight of FDRs to ensure they are adhering to Standards of Conduct and P & Ps?			

# Compliance Plan Effectiveness Self Assessment Tool

<b>ELEMENT I: Written Policies and Procedures and Standards of Conduct</b>			
<b>Description</b>	<b>Yes</b>	<b>No</b>	<b>Evidence of Compliance or Action Required</b>
Do your P & Ps describe in detail how potential compliance problems are investigated and resolved?			
Do your P & Ps describe with specificity how to communicate compliance issues to compliance personnel?			
Does the Board of Directors or a subcommittee of the Board of Directors review and approve Standards of Conduct and new and revised P & Ps?			

# Compliance Plan Effectiveness Self Assessment Tool

## What it is:

- Checklist to help evaluate compliance program design
- Resource to identify program strengths and weaknesses
- Aid to develop and improve key components of an effective program

## What it isn't:

- Regulatory guidance
- All-inclusive list of compliance program requirements

# Compliance Plan Effectiveness - Governing Body & Senior Management Oversight

- Proper relationship between Board and Compliance Officer is critical to an effective compliance program
- Without board access, the CO may be faced with road blocks by senior management in efforts to prevent, identify or correct wrongdoing
  - Statistics show that without direct reporting to the Board, 35% of public and 15% of private companies ' compliance executives stated that reports by the Compliance Officer are always screened and/or substantively edited by the general counsel or some other executive.
- Discussions with CEOs during the audit process revealed that non-compliance issues were getting stuck at various levels of the organization

Sources: The Relationship Between the Board of Directors and the Compliance and Ethics Officer, a survey by the Society of Corporate Compliance and Ethics and the Health Care Compliance Association

# Compliance Plan Effectiveness – Independence of Medicare Compliance Officer

- Direct report to CEO or Corporate CO; Not to General Counsel
- Unfiltered periodic (quarterly) report to Board or Committee of Board
- Severance provisions in employment contract
- Termination only with approval of Board

# Compliance Plan Effectiveness – Governing Body & Senior Management Oversight

HHS IG Daniel Levinson – Comments From July 2010 Article in Trustees Magazine re: Hospital Trustee Engagement and Hospital Success:

- “The best boards are active, questioning and even skeptical”; “they don’t make assumptions, they don’t view their jobs in narrow terms and they don’t shy away from asking some very tough questions.”
- “The Board’s fiduciary responsibility simply cannot be fulfilled” unless examining the nitty-gritty details of how the entity is doing.
- “Every Board needs a system in which it can get candid information on how the [entity] is doing in a timely, comprehensive manner because communication is critical. Reports should be presented in a way that is clear and easily understood, sometimes in the form of dashboards, scorecards or other graphic presentations. “

## Compliance Plan Effectiveness – Governing Body & Senior Management Oversight

- “Compliance officer can be more effective if he or she does not also serve as legal counsel.”
- “Compliance officer should [serve like an ombudsman] and report directly to the board of trustees, with no buffer in between. Trustees need unfiltered [unbuffered] guidance to truly understand how well institutions are doing. They need a person paid to deliver the news on how well [things are going] especially when the news isn’t positive”
- Note: OIG Corporate Integrity Agreements (CIAs) have language re: affirmative obligation of Board to conduct oversight, for CO to report directly to CEO and make reports to the Board and for CO to not be subordinate to GC/CFO

# Compliance Officer Best Practices

- Meet with managers and attend business operations meetings
- Observe operations personnel doing their jobs (e.g., sit in at Call Center; visit FMOs)
- Survey employees about attitudes towards compliance; conduct focus groups
- Coordinate with HR for exit interviews
- Celebrate improvements with operations

# Organizational Best Practices

- Have compliance expertise on Board/audit or compliance committee of the Board
- Board Agenda includes compliance as standing agenda item
- Board minutes detailed and reflect discussion and resolution of compliance issues
- Regularly educate Board on compliance program/risks in order to properly exercise independent judgment and oversight
- CO does not report to GC/CFO
- Publicize (de-identified) disciplinary actions (transparency changes behavior)
- Quantifiable effectiveness measurement (where you are and whether improvements made)

# Organizational Best Practices

- Business leaders held accountable for compliance results (performance evaluations, incentives, etc)
- Complaints (employees, beneficiaries, providers, FDRs) taken seriously and are analyzed for trends
- Education is not enough to change behavior – also need incentives and/or disciplinary consequences
- FDRs - centralized contracting oversight operations and insert compliance terms with monetary consequences for violations

# Wrap Up

## Contact information

[brenda.tranchida@cms.hhs.gov](mailto:brenda.tranchida@cms.hhs.gov)

(410) 786-2001

[marianne.bechtle@cms.hhs.gov](mailto:marianne.bechtle@cms.hhs.gov)

(410) 786-5080

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