

# Audit, Enforcement and Compliance Plan Overview and Update

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## Today's presentation

- 2010 Enforcement Update
- 2010 Audit Update
- Compliance Plans



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## 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



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## 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



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## 2010 Enforcement Actions

All enforcement letters posted and publicly available on CMS website

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



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## 2010 On-Site Audits

- All conducted at parent organization level
- Selection based on risk assessment
- Quality assurance and quality improvement goals
- 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
- 6 enforcement actions utilized audit results
  - 1 Termination
  - 5 Marketing/Enrollment Sanctions
  - Ineffective compliance plan cited in 5 out of these 6 actions



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## 2010 On-Site Audits

- Audit 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)



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## 2010 On-Site Audits

- Approach:
  - “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



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## 2010 On-Site Audits

- Corrective Action Process:
  - 60 calendar days to correct from date of report
  - Attestation from CEO
  - 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)
- Audit results posted on CMS web



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## 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



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# Compliance Plans

- 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



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# Compliance Plans

- Among other important updates, 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]



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## Compliance Plans

### 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)



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## 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



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## 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.)



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## 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



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## 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



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## 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)



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## 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



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## Wrap Up

### Contact information

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