

Mandatory Compliance Plans

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Today's presentation

- Compliance Plan Requirements Update
- 2010 Audits/Effectiveness Evaluations
- Self-Assessment Tools
- Governing Body and Senior Management Oversight



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Requirements Updates – CMS Regulations

Key Changes:

- Element 1:
 - Specific provisions must be included (e.g., non-retaliation policy) in policies and procedures/standards of conduct to implement operation of compliance program
- Element 2:
 - Governing body must: (1) be knowledgeable about content and operation of the compliance program; and (2) exercise reasonable oversight for implementation and effectiveness of program
 - CO/CC must periodically report directly to the governing body of organization on activities/status of program, including issues identified, investigated and resolved



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Requirements Updates – CMS Regulations

- Element 3:
 - Chief executive, managers and governing body must receive compliance training and education
 - Training and education must occur at least annually and upon hire, for new chief executive, Board members, and managers and for any new FDRs
 - First tier, downstream and related entities (FDRs) that have met fraud, waste and abuse (FWA) certifications through enrollment in FFS Medicare program or accreditation as a DMEPOS suppliers deemed to have met the FWA training and education requirement
 - However, Medicare program compliance training and education still required.



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Requirements Updates – CMS Regulations

- Element 4:
 - Lines of communication must allow for confidential, and at least one method of anonymous, good faith reporting of potential compliance issues as they are identified
- Element 5:
 - Well publicized disciplinary standards that articulate expectations for reporting and assisting in resolution of compliance issues, identify non-compliance or unethical behavior and provide for timely, consistent and effective enforcement of standards when detected



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Requirements Updates – CMS Regulations

- Element 6:
 - Effective system for routine internal monitoring and identification of compliance risk areas by business units and periodic internal audits to confirm compliance.
 - External audits as appropriate, including of first tier
 - Evaluation of overall effectiveness of the compliance program
- Element 7:
 - System for prompt response and prompt, thorough and appropriate correction
 - If the sponsor discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely reasonable inquiry and institute correction including, e.g., repayment of overpayments and discipline.
 - Procedures for voluntary self-reporting of potential fraud or misconduct



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Other Related Health Care Program Changes

- 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



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Other Related Enforcement Changes

- Federal Sentencing Guidelines Amendments, effective 11/1/10 – Manual, Chapter 8 (section B2.1) (standards for an “effective compliance and ethics program”)
- Key change – lower culpability score when compliance and ethics program leaders (CO) have “direct reporting obligations” to the Board.
- Defined: CO has “express authority to communicate personally to the Board promptly on any matter involving criminal conduct or potential criminal conduct and no less than annually on the implementation and effectiveness of the compliance and ethics program”.



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2010 On-Site Audits

- On-site
- Quality assurance and quality improvement goals
- 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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2010 On-Site Audits

- All conducted at parent organization level
- Selection based on risk assessment
- 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 program at all sanctioned organizations.



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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)
- Audit results posted on CMS web



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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

- 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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Corrective Action/Validation Process

- **Timelines & Senior Leadership Involvement**
 - 60 calendar days to correct deficiencies
 - Requires engagement & ownership by the CEO and BOD
 - Attestation from CEO assuring deficiencies have been corrected and not likely to recur
 - Board of Directors resolution – quarterly meetings to review and evaluate effectiveness of compliance program
 - Aligns with new compliance program regulations
 - What assurances does the CEO need to see/validate from staff before attesting to CMS?



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Corrective Action/Validation Process

- **Corrective Action and Validation Submission (Part I)**
 - No longer a “corrective action plan” and P&P review
 - Requires active participation from compliance and operational areas
 - Sponsor must be able to fully articulate and demonstrate evidence of correction
 - Corrective action should be descriptive and tell a story of steps taken towards fixing problems



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Corrective Action/Validation Process

- **Corrective Action and Validation Submission (Part I)**
 - At a minimum, submission to CMS must include the following:
 - Description of finding
 - Reference number/tabs to connect narrative with supporting evidence
 - Owner of the Process/Remediation for each deficiency
 - 4 stages (*Identification, Solutions, Implementation, Testing*)
 - Approach to measuring effectiveness
 - Internal Controls to ensure ongoing compliance
 - Control/Monitoring Frequency
 - Target and Completion Dates
 - Medicare Compliance Officer sign off
 - Date of Board discussion



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Corrective Action/Validation Process

- **Understanding the Correction – (Part II)**

- Once the submission has been forwarded to CMS for review, we would like the following:

- **(1) Executive Summary of Organizational Changes**

- Before and after overview
- What did the organization look like before the audit?
- What structural and process changes have occurred after the audit?
- Changes in organizational culture
- Performance Monitoring - How does the compliance department evaluate the compliant status of business operations and oversight over external entities?



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Corrective Action/Validation Process

- **Understanding the Correction – (Part II)**

- **(2) Walkthrough of corrective action by the Compliance Officer and/or CEO**

- To fully understand your progress
- Various methods of demonstration available
- In person, webinars, video-conferencing, conference calls
- Be prepared to answer questions concerning solutions and testing procedures
- The Compliance Officer's commitment through the review process to answer questions and provide clarification



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Compliance Audits Key Deficiencies

- 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 Audits Key Deficiencies

- 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 Audits Key Deficiencies

- 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 Audits Key Deficiencies

- 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 Medicare program compliance/detect FWA



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Compliance Audits Key Deficiencies

- 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 Audits Best Practices

- Effective training modules – provide real-life scenarios specific to operational areas
- Compliance is integrated in the business/operational areas (compliance professional assigned to each operational area, i.e., marketing, appeals & grievances, enrollment, etc.)
- Centralized compliance and business operations
- Identifying the root cause of CMS-issued warning letters, notices of non-compliance, and CTM complaints
- Streamlined process for distributing HPMS notices – following up with business owners to ensure they understand the policy and implementation and training has occurred. Place internal controls to periodically test the processes to ensure they are working and consistent with the current policies and procedures



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Compliance Audits Best Practices

- Three-way reporting and communication between the Compliance Officer, CEO, and Board of Directors
- Board and Compliance Committee meeting minutes demonstrate substantial issues are discussed and follow-up action is well documented
- Frequent Risk Assessments
 - set of indicators, data and reports to identify where risks are within your organization
- The CEO and BOD is engaged and involved in the development and implementation of compliance policies and procedures and endorses ethical values and code of conduct.
 - Intranet
 - Print or video messages
 - All staff meetings
 - Align incentives with compliance & performance results



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Compliance Plan Effectiveness

Structure: the building blocks and framework

- “Culture” of compliance and ethics endorsed by leadership
- Data and information exchange between the Compliance Officer, Senior Executives, Governing Body, and employees
- Policies & procedures
- Reporting mechanisms
- Education & training



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Compliance Plan Effectiveness

Process: How your system actually works

- Ongoing risk assessments & monitoring activities
- Incorporating new regulatory and policy changes
- Response and prevention
- Enforcement and discipline
- Systemic corrections
- Accountability of operational areas to compliance department



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Compliance Plan Effectiveness

Outcomes: What results are achieved? How do you know it's working?

- Monitoring and audit results trigger a need for updated procedures and retraining employees
- Proper internal controls over delegated entities performing operational functions
- Employee engagement and awareness
- Excluded providers are screened out using OIG and GSA debarment lists
- Decrease /Increase in Medicare beneficiary and PBM fraud, waste, and abuse
- Evaluate the effectiveness of your compliance plan



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Compliance Plan Effectiveness

Structure (7 required foundational elements) x

Process (how you communicate and work together) x

Outcomes (are you finding and fixing? e.g., are you detecting issues at earliest opportunity, reducing number and severity of non-compliance?) =
EFFECTIVENESS



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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.



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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.
- Ignores monitoring; 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



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Other Relevant Guidance - Effectiveness

DOJ Principles of Federal Prosecution of Business Organizations, Corporate Compliance Programs, Chapter 9-28.800:

- Apply a set of critical factors to determine :
 - Is the program being applied earnestly and in good faith and does the program work?
 - Is it well designed and comprehensive?
 - Are employees adequately informed about the compliance program and convinced of the entity's commitment to it?
 - Are internal audit functions conducted at a level sufficient to ensure independence and accuracy?



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Other Relevant Guidance - Effectiveness

- Have the directors established an information and reporting system reasonably designed to provide timely and accurate information sufficient to allow informed decision-making regarding compliance?
- Has the entity provided for a staff sufficient to audit, document, analyze and utilize results of the compliance efforts?
- Are revisions to the program made in light of lessons learned?
- Is the compliance program designed to detect the particular types of misconduct most likely to occur in a particular entity's line of business?



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CMS Compliance 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.hcca-info.org/Content/NavigationMenu/ComplianceResources/ComplianceBasics/CompEvalCheckList.pdf>



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CMS Compliance Self Assessment Tool

ELEMENT I: Written Policies and Procedures and Standards of Conduct			
Description	Yes	No	Evidence of Compliance or Action Required
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?			



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CMS Compliance Self Assessment Tool

ELEMENT I: Written Policies and Procedures and Standards of Conduct			
Description	Yes	No	Evidence of Compliance or Action Required
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?			



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CMS Compliance Self Assessment Tool

ELEMENT I: Written Policies and Procedures and Standards of Conduct			
Description	Yes	No	Evidence of Compliance or Action Required
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?			



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CMS Compliance Self Assessment Tool

What it is:

- A checklist to help evaluate compliance program design
- A resource to identify program strengths and weaknesses
- An aid to develop and improve key components of an effective program

What it isn't:

- Regulatory guidance
- An all-inclusive list of compliance program requirements



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Governing Body, Senior Management Oversight

- Proper relationship between Board and Compliance Officer is critical to an effective compliance program
- Without board access, the compliance officer may be faced with road blocks by senior management with their 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



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Other Relevant Guidance – Governing Body and 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. “



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Other Relevant Guidance – Governing Body and 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

Wrap Up

What have we learned and how can we promote improvement?

Wrap Up

- Promoting the implementation and maintenance of effective health care compliance programs is key!
- We have examples of when these programs work effectively (e.g., significant change and improvement occurs when Boards are informed, CEOs are aware and engaged and COs have the ability to have unfettered access to the CEO and Board)
- We have examples of when they don't work effectively (our enforcement actions –in every case ineffective compliance program)



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Wrap Up

Feedback and Dialogue Welcomed

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