

Compliance Program Element VI

Monitoring, Auditing and Identification of Compliance Risks



Focused Training

Compliance Program

Guidelines

Vernisha Robinson, MSM, CHC

Philip Sherfey, JD, CHC

CM/Program Compliance and Oversight Group,
Division of Compliance Enforcement

Beth Brady, CFE, AHFI

Center for Program Integrity, Division of Plan Oversight
and Accountability

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Today's Agenda

Part I – Overview of Element VI Requirements

Part II – Case Study: The RutRo Case;
Lessons Learned; Evaluating Effectiveness

Part III – Questions and Answers Session

Part I – Overview of Element VI

Element VI

Routine Monitoring, Auditing and Identification of Compliance Risks

Must establish and implement an effective system for routine monitoring and identification of compliance risks:

- Internal monitoring and audits
- External audits, as appropriate
- Monitor/audit sponsor and first tier, downstream, and related entities (FDRs)
- Compliance with CMS requirements
- Effectiveness of Compliance Program

“Must” ... “Should” ... “Best Practices”

- Must:*** Requirements created by statute or regulation; no discretion
- Should:*** Expectations identified in Guidelines; discretion as to how you accomplish effectiveness
- Best Practices:*** Procedures that work well for some Sponsors; may not work for all

Routine Monitoring and Auditing

Monitoring: Regular reviews performed as part of normal operations, to confirm ongoing compliance

Auditing: Formal reviews of compliance, with particular set of standards as base measures

System to Identify Compliance Risks

- Must conduct a formal baseline assessment of major compliance and fraud, waste and abuse (FWA) risk areas (*e.g., risk assessment*)
- Must take into account all Medicare business operational areas
- Examples provided in Guidelines of high risk areas for Medicare Parts C and D Sponsors
- Transfer results into a monitoring and auditing work plan

Example: Medicare C/D Risk Assessment

- What tool is used to assess compliance risks across the Medicare business?
- What are the areas of focus?
 - Areas of concern identified by CMS
 - Areas of concerns identified by the Sponsor
 - Areas of concern identified by beneficiaries, providers, or other business practices?
- What are your risk levels? (e.g., high, medium, low)
- Color coded, point system, probability/impact
- CMS Readiness Checklist, Annual Call Letter, Enforcement and Compliance Actions, OIG work plan

Example: Medicare C/D Risk Assessment

Medicare Areas	Consequences/ Impact	Probability/ Likelihood	Reason / Action Required	Priority Ranking / High Risk
Compliance Program Effectiveness	MEDIUM	Likely	Chapters 9/21; FDR oversight measures and procedures needed; audit program effectiveness	4
Accountability for and Oversight of FDRs	MEDIUM	Likely	Requires new training & communication & auditing plan with FDRs (PBM, providers, call centers)	5
Part C ODAG	VERY HIGH	Very Likely	Extremely important potential to cause death	3
Part D CDAG	VERY HIGH	Very Likely	Extremely important potential to cause death; Senior management involvement	2
Enrollment	LOW	Unlikely	New CMS guidance requires P&P update	6
Transition Policy	VERY HIGH	Very Likely	Extremely important potential to cause death	1

Monitoring and Auditing Work Plan

- Based on results of risk assessment
- Compliance Officer coordinates with operational departments
- Outlines monitoring/auditing specifics
- Includes process for responding to results
- Corrective actions overseen by Compliance Officer/Dept.

Audit Schedule and Methodology

- Lists all monitoring/auditing for calendar year
- Operational areas and First Tier entities
- Combination of desk and on-site audits
- Prepare Audit Report
- Targeted samples/techniques
- Use CMS Performance Audit Protocols and Best Practices/Common Findings from Audits

Example: Monitoring Work Plan

Function	Department/ Person Responsible	Frequency	Desk or Onsite	Monitoring Highlights and Issues of Concern
Member Services	John Doe	Daily	Onsite	Review of calls for misrouting and/or transferred to ops area for F/U
Compliant Tracking Module (CTM)	Donna Doe	Daily Weekly	Desk	Review of CTM volume by type with a focus on access to care / Rx issues; Review 30 CTM cases for appropriate timeliness/resolution & communication with CMS
Org. and Coverage Determinations, Appeals, Grievances	Richard Roe	Weekly	Onsite	Review of 25 Part C org. determination notices and 25 Part D covg. determination notices; review 30 grievances for appropriate processing/resolution
Formulary Administration	Paula Poe	Daily	Desk	Daily review of rejected claims; compare website files with HPMS approved files

Example: Auditing Work Plan

Auditing Activity	Audit Start Schedule	Appropriate Methods Used	Audit Results	Corrective Actions
Part C Appeals/ Grievances	Q1 – 2013 February 3-15	Sample notices sent to 50 members; interview A/G staff; system logs	23/50 = 46% compliant; interviews with staff- confused or unaware of CMS new requirements and recent HPMS notice w/updated guidance	Immediate re-review member issues by management; training and education
Sales/Marketing Material	Q2 – 2013 May 15-25	Samples of marketing material, P& P reviews, CTM cases	10 pieces of unapproved materials were used by Sponsor & agents	Discuss with RO AM; discuss internal controls with Marketing dept.; develop CAP

Audit of Operations and Compliance Program

- Audit function may be a separate department or performed by the Compliance department
- *Routine Monitoring* performed internally (each operational area) and by Compliance Dept.
- *Auditing*: No self-policing by operational areas; must be independent auditors, internal audit or compliance
- Must audit the effectiveness of the compliance program and share results with governing body

Monitoring and Auditing FDRs

- Must develop a system to monitor and audit **first-tier** entities
- Must ensure **first-tier** entities fulfill compliance program requirements
- Must ensure **first-tier** entities monitor compliance of downstream entities

Monitoring and Auditing FDRs

Administrative/Management contracts or agreements with a delegated entity to perform or handle all or a portion of the following functions:

- Claims Administration, processing and adjudication functions
- Enrollment, disenrollment, and membership
- Marketing, including delegated sales brokers and agents
- Credentialing
- Call Center Operations
- Financial Services
- Information Technology
- Perform, implement or operate any aspect of the Part C and/or D operations

FDR Risk Assessment

For purposes of the Compliance Program requirements...

- **If Sponsor has a large number of first tier entities, making it impractical and/or cost prohibitive to monitor all its first tier entities, Sponsor may perform a FDR risk assessment.**
 - Identify highest risk first tier entities
 - Select a reasonable number of first tier entities annually from the highest risk groups
 - Explain the functions and risks associated with the first tier entity; frequency and level of monitoring/auditing
 - Compliance metrics
- Must ensure first tier entities are applying appropriate compliance program requirements to downstream entities with which the first tier contracts

Monitoring and Auditing FDRs

- Pre delegation audits?
- Frequency – monthly, quarterly, annually?
- Audit tools? (ex. checklist, sampling, interviews, etc.)
- Defined objective and scope?
- Delegation Oversight committee?
- Compliance Dept. only or multi-party involvement?
- Who is responsible for communicating FDR audit results and implementing required corrective actions?
- What happens when the FDR's performance is below the Sponsor's or CMS compliance standards?

Example: First Tier Entity Table

Microsoft Excel - Book1											
	A	B	C	D	E	F	G	H	I	J	K
1	Entity Description	Type	Delegated Functions								
2			Claims Processing	Utilization Management	Pharmacy Coverage Determinations	Credentialing	Call Center Operations	Provider/Facility Contracting	Member/Marketing Material	Part C Appeals and Grievances	Part D Appeals and Grievances
3	ABC Prescriptions	PBM	X		X	X		X			X
4	Mail R Us	Member Notices & Materials							X		
5	Orthopedics USA	Prosthetics and Orthotics	X	X		X	X				
6	XYZ Company	Outbound Enrollment Verification					X				
7	QRS, Inc.	OIG/GSA exclusion lists verification									
8	Market 4 You, Inc.	FMO				X			X		
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Tracking and Documenting Compliance

- Sponsors should track and document compliance efforts
- Dashboards, scorecards, self-assessments tools and other mechanisms help demonstrate compliance goals and achievements
- Issues of noncompliance and potential FWA identified in the assessment tools should be shared with senior management

CMS Compliance Program Self-Assessment Questionnaire (SAQ)

- Attachment V (Rev. 3, 12-2012) – 2013 Program Audit Process and Protocols
- Should not interpret every question as a mandatory CMS requirement, but rather as a guide in evaluating the effectiveness of their Compliance Program.
- Structure of the SAQ
 - Number
 - Description = Regulations, Policy Requirements and Expectations
 - Yes or No
 - Documentation = Where are the compliance efforts documented?
 - Responsible Party/Department = Who is involved?
- Use this tool as a monitoring/auditing tool and if necessary, add questions fit your organization's structure and needs

CMS Compliance Program Self-Assessment Questionnaire

Element III: Effective Training and Education

42 CFR §422.503(b)(4)(vi)(C) and 42 CFR §423.504(b)(4)(vi)(C)

	Description	Yes	No	Documentation	Responsible Party or Department
	potential FWA?				
21.	Do you provide training on FWA risks based on the individual's job function?				

Element IV: Effective Lines of Communication

42 CFR §422.503(b)(4)(vi)(D) and 42 CFR §423.504(b)(4)(vi)(D)

	Description	Yes	No	Documentation	Responsible Party or Department
22.	Do you have an effective method(s) to communicate information from your compliance officer to others, within a reasonable time frame, including changes in laws, regulations and sub-regulatory guidance as well as changes to your Standards of Conduct and Ps & Ps?				
23.	Do your Standards of Conduct				

Dashboards and Scorecards

- **Medicare Part C/D Dashboard**

- Heavy focus on metrics related to high risk functions, Notices of Non-Compliance, Warning Letters, Enforcement Activity
- Provides business areas and senior management with monitoring metrics and results
- Weekly, monthly, daily trends against Sponsor's or CMS targets
 - % Enrollment Submitted Within 7 days
 - PDE Reject Rates
 - % denial rate for Part C and D Coverage Determinations
 - % within Compliance - G & A Turnaround time
 - % Untimely Appeals sent to Maximus
 - % of CTM Cases Returned by CMS for Inappropriate Closure
 - % of Immediate CTM complaints handled within 48 hours
 - % of Protected Claims Transitioned
 - % of OEV calls Attempted within CMS timeframes
 - Aging and Turnaround for Part C and Part D claims

OIG/GSA Exclusions

Review the DHHS OIG and GSA exclusions lists **prior to** hiring or contracting, and **monthly**:

- New and Temporary Employees
- Volunteers
- Consultants
- Governing Body members
- FDRs

Use of Data Analysis for FWA Prevention and Detection

- Establish baseline data to recognize unusual trends or changes in utilization or patterns over time
- Identify internal problem areas such as enrollment, finance, or data submission, and problem areas with the FDRs
- Use findings to determine where there is a need for policy changes

Special Investigations Units (SIUs)

SIU - An internal unit, often separate from the compliance department, responsible for investigation of potential FWA

- Sponsors not expected to perform law enforcement duties-may refer FWA matters to NBI MEDIC or law enforcement
- SIUs must be accessible via phone, email, Internet and mail
- Sponsors must ensure FWA can be reported anonymously
- Communication and coordination between SIU and Compliance Department is critical

Auditing by CMS or its Designee

- CMS has discretionary authority to audit
- Includes records of FDRs
- Thorough review of documentation
- Burden on sponsors to demonstrate compliance

Part II – Case Study and Lessons Learned

Case Study

RutRo Health Plan, Inc.

RutRo Health Plan, Inc.

- MA, MA-PD
- Commercial enrollment: 1 million
- Medicare enrollment: 125,000
- Wholly owned subsidiary of a public company
- Corporate headquarters in Texas
- Medicare operations in Maryland

RutRo: Poll – Auditing of Compliance Program Effectiveness

- 1. Which department is NOT permitted to conduct audits of the effectiveness of the compliance program?**

- A. Compliance Department
- B. Internal Audit Department
- C. Special Investigations Unit (SIU)
- D. Operational Departments

Answer: A

Compliance Department

- The Compliance Department is not permitted to perform the audits of the effectiveness of the compliance program. Audits must be performed independently, to avoid self-policing.

RutRo: Poll – OIG and GSA Exclusions Screening

- 2. When must exclusion screening be performed for employees and FDRs?**
- A. Prior to hire/contracting
 - B. Monthly
 - C. Both A and B
 - D. None of the above

Answer: C

Both A and B

- Sponsors must review the DHHS Office of Inspector General (OIG) and the General Service Administration (GSA) exclusion lists prior to hiring or contracting any new employee or FDR, and monthly thereafter, to ensure these persons or entities are not excluded or become excluded from participating in federal programs.

RutRo: Poll – Compliance Monitoring Tools

- 3. Which of the following tools can be used to monitor compliance?**
- A. Dashboards
 - B. Scorecards
 - C. Self-Assessments
 - D. All of the above

Answer: D

All of the above

- Compliance monitoring may include use of dashboards, scorecards and self-assessments to track and document compliance.

RutRo: Audit Results

A review of various documents concerning routine monitoring and auditing and discussions with a variety of business area directors and senior management reveal...

- One risk assessment performed is for the entire enterprise and all lines of business (*commercial, Medicare, Medicaid, long-term care, etc.*); risks are group together
- HPMS notifications are reviewed by the Compliance Department and emailed to operational areas – no follow-up
- General work plans; no timeframes or correlations with risk assessment
- Self- auditing by the operational areas. Audit results never verified by Compliance Department.
- Limited resources; audit staff unaware of current CMS requirements

RutRo Poll: Audit Results

- 4. Which of the following areas are non-compliant with CMS compliance program requirements and need improvement?**
- A. Risk Assessment
 - B. Monitoring and Auditing Work Plans
 - C. Internal Audit Function
 - D. FWA Data Analysis
 - E. All of the Above

Answer: E

All of the above

- Compliance Program Guidelines - Section 50.6 and its sub-sections provides specific requirements and expectations for Medicare Parts C and D risk assessments, work plans, internal audit function, FWA analysis.

Lessons Learned: Ineffective Compliance Practices

- Lack of coordination
- Poor workflow
- Reduced responsiveness
- Conflicting communications
- Gap in skills
- Excessive conflict /unclear roles and expectations for staff
- Random audits, not based upon risks
- Not performing ongoing monitoring of operational areas
- Audits not conducted by independent parties
- No audit conducted of Compliance Program
- Little oversight of FDRs- presume compliant

Lessons Learned: Best Practices

- Regular reporting of monitoring/auditing results to senior management and Board
- Variety of audit methods (desk, onsite, internal, external, etc.)
- Regular audits of high-risk areas
- Department dedicated to Delegated Entity Oversight
- Compliance personnel interact with operational personnel; decision-making personnel are at the table when developing risk assessments and auditing procedures

Evaluating Effectiveness

- **What is your plan and desired outcome for your Medicare compliance program?**
- **Systematic process of internal controls** that provides reasonable assurance that the Sponsor and its first tier, downstream and related entities (“FDRs”) will prevent, detect and correct Medicare program noncompliance and FWA. *(Elements 1, 2, 3, 4, 5, 6, and 7)*
- Includes an **organizational strategy – a risk assessment and an auditing and monitoring work plan and corrective action process** – that is designed to and is reasonably successful in *finding and effectively fixing* noncompliance and FWA *at the earliest possible time*. Detects risks and vulnerabilities in its operations and promptly corrects weaknesses or devises CAPs. *(Elements 6 and 7)*

Evaluating Effectiveness

- **Addresses the organization's risks**, regardless of how they are identified, such as through a formal risk assessment, beneficiary complaints, regulatory enforcement and monitoring and auditing results, among others. *(Element 7)*
- **Monitors operational compliance** and tracks and trends incidents of noncompliance. *(Element 6)*
- **Examines the occurrence of multiple identical issues** to determine if they are systemic rather than single, unrelated incidents. *(Element 7)*
- Undertakes a **root cause analysis** to determine the root cause of noncompliance. *(Element 7)*

Evaluating Effectiveness

- **Responds promptly** to compliance issues and potential FWA as they occur. *(Element 7)*
- **Mitigates risk areas over time.** The expectation is not perfection in operational compliance but significant improvement in problem areas over time. Audits and monitoring will reveal fewer errors in risk areas addressed through the compliance program. *(Element 6)*
- **The compliance officer, compliance committee, CEO, senior management and the board, as well as impacted business managers are aware of the operational areas with significant noncompliance and of what is being done to correct them.** *(Elements 2 and 4)*

Evaluating Effectiveness

- Significant operational compliance challenges are reported to the CEO and to the Board Audit Committee and are addressed in the compliance committee. **Meeting minutes or other documentation reflect organizational oversight of the issue.** (Element 2)
- **Monitors corrective actions over time** to ensure that they are effective in preventing errors. Progress and results are assessed and reported regularly. If it is determined they are not effective, corrective actions are revised until monitoring and tracking demonstrates sustained improvement. (Elements 6 and 7)
- **Takes disciplinary action when indicated appropriately** in view of the violation, consistently and timely. (Element 5)

Effectiveness Measure:

Tracing Issues through the Compliance Program

- Use current or past operational issues and trace them through your compliance program (*e.g., CTMs, deficiencies detected via monitoring/auditing, CMS RO Account Manager, PBM, FDRs, NONC, Warning Letters, etc.*)
- Gather information and documentation which may be located in different departments, areas, or sources
- Interview subsets of employees from all levels (top, middle, bottom) to receive information, confirm facts, and decide best approach
- Sit in the impacted area and observe accountability and compliance issues/challenges
- Evaluate the evidence!

Effectiveness Measure:

Tracing Issues through the Compliance Program

- Detailed Policies and Procedures distributed or made available to employees? (Element 1)
- Was the compliance issue considered or acted on by the Compliance Officer and the Compliance Committee? (Element 2)
- Was the compliance issue reported to senior management/CEO or Board? (Element 2)
- Training and education of staff involved with this issue? (Element 3)
- Appropriate communication between Compliance Officer and Staff (Element 4)

Effectiveness Measure: Tracing Issues through the Compliance Program

- Consistent, timely, and appropriate disciplinary action, if any (Element 5)
- Was this compliance issue or area identified on risk assessment? (Element 6)
- Monitoring and Auditing – spot checks, tracking and trending compliance, results analyzed and reported? (Element 6)
- Root Cause Analysis and/or FWA Detection? (Element 7)
- Timely Corrective Action Implemented and Effectiveness (Element 7)

Part III – Questions and Answers Session

Questions and Answers Session

- In preparation for today's focused training, we requested that sponsors submit questions to the Medicare Parts C and D Compliance Program Guidelines mailbox.
- CMS will now provide verbal answers to pre-submitted questions
- All Qs & As from training session to be formalized and distributed at later date

Questions/Answers

The Division of Compliance Enforcement (DCE) has a streamlined process for responding timely to compliance program policy questions or inquiries:

Parts_C_and_D_CP_Guidelines@cms.hhs.gov

The Part C and Part D Compliance and Audits webpage provides information regarding Compliance Program Policy and Guidance, Compliance and Enforcement Actions taken by CMS, and Program Audits relating to Medicare Plans.

<http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/index.html>