

Session 502

Effective Compliance Oversight:

The Role of Compliance vs. The Role of Operations

Your Speakers Today



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Slide 2

- 3 **Pending Picture**
Albert Aguilar (US - Assurance), 1/4/2018

Agenda

#	Focus
1	Introduction and Background
2	Compliance structures and business involvement
3	The Three Lines of Defense
4	Spotlight: Compliance Monitoring
5	Achilles Heel? FDR Oversight!
6	Q&A

Today's objectives

- Understand the differing roles and responsibilities of managed care compliance and operations related to compliance standards
- Evaluate the different structures and models to ensure compliance coverage
- Understand the three lines of defense and how they relate in the identification and mitigation of compliance risk
- Review examples of functional areas and the potential roles of compliance and operations



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1. Introduction and Background

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Defining compliance roles and responsibilities

Emerging risks underscore the urgency for Compliance to not only change how it partners with the business but also clarify roles and responsibilities between its function and that of Operations

- **Big "C" Compliance and little "c" operational compliance:** Roles and responsibilities are clearly defined where Operations "owns" (accountable, responsible for) day-to-day compliance and the Compliance Department "owns" **the infrastructure to drive compliance behavior throughout the organization.**
- **Centralized vs. Decentralized vs. Hybrid Structures:** Organizational models are designed to **align with the business organization's strategy**, while **providing flexibility** as the organization grows and changes.
- **Convergence and Business Diversification:** Continuous **growth of the organization's business** requires **new skill sets**, different approaches to **coordinating across stakeholders** and **refined capabilities** to look at data and process impacts differently.
- **Implementing Member-Centric Risk Management:** Playing at the intersection of Compliance, Customer Experience and Operations, the Compliance function can use its **view across the entire value chain** in playing the **role of a strategic advisor** to the business.
- **Evolving Analytics:** Compliance needs to be at the forefront of **transforming data into information** and of **leveraging analytics** for monitoring, auditing and advising the Board and C-suite as well as empowering regulators in the oversight of payers.
- **Achilles Heel: Delegated entity / vendor management oversight** becomes increasingly difficult with the diversification of products, thus requiring Compliance to play a **more hands-on role in risk-based oversight** and collaborating with vendor/entity owners.

Comparison of Compliance and Business Roles

Key Roles of the Compliance function:

- Identify and assess compliance risks
- Develop standards and expectations across the organization
- Keep up to date with regulatory requirements and communicate appropriately
- Coordinate and monitor implementation of compliance activities in business units/ areas
- Establish and provide foundational operational compliance activities (e.g. hotline, tools, standard reporting, policy management, Code of Conducts)
- Assess effectiveness of compliance controls and activities
- Analyze root cause of compliance issues identified, plan remediation and report progress/outcomes

Key Roles of the Business Operations and Other functions:

- Identify applicable compliance risks / requirements
- Monitor results of Key Performance Indicators (KPIs)
- Gather and provide compliance information to Compliance function and senior management
- Customize activities to meet business unit risks and local laws and regulations
- Ensure that employees know their roles and are properly trained to execute them.
- Monitor/Audit employee performance
- Vendor oversight and monitoring

Compliance partners with operational stakeholders to develop corrective action and implementation plans

The business “owns” compliance; management is “accountable.”

Risks from lack of collaboration between Compliance and Business Operations

- Poor communication / reporting between Compliance and Business Operations lead to silos amongst teams, including Senior Leadership
- Failure to achieve strategy and business goals
- Fostering a reactive v. a proactive culture
- Inaccurate risk assessments, lead to inefficacy to mitigate potential regulatory risks
- Inability to efficiently respond to an unfortunate event (i.e. Fraud Investigations)
- Lack of significant resources dedicated to compliance and operational functions (e.g. policies, procedures, controls, trainings, etc.)
- Lack of trust with regulators
- Penalties for noncompliance, including fines, sanctions, suspension or exclusion.



2. Compliance Structures and Business Involvement

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Governance and oversight of compliance

Board of Directors

- Significant compliance issues / audits findings and planned corrective actions
- Significant regulatory updates and plans for implementation
- Code of Conduct updates/revisions
- Risk trends and mitigation

Compliance Committee

- Audit findings and planned corrective actions
- Regulatory updates and plans for implementation
- Compliance issues identified, results of root cause analysis, and remediation plan
- Compliance policy and Code of Conduct updates / revisions
- Compliance plan
- Risk Management

Operational stakeholders

- Addressing findings related to their functional areas
- Regulatory updates impacting their functional areas
- Compliance issues identified in their functional areas
- Monitoring results of Key Performance Indicators (KPIs)
- Compliance policy and Code of Conduct updates / revisions
- Vendor Oversight

Compliance partners with operational stakeholders to develop corrective action and implementation plans

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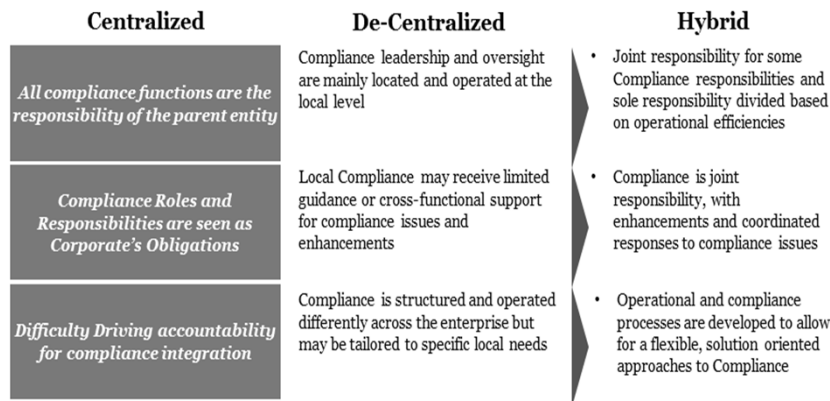
Compliance structure and governance considerations

	Compliance Structure and Governance Considerations	Impact
Structure of Function:	<ul style="list-style-type: none"> • Benefits of centralized, decentralized and hybrid structure • Structure of the wider organization • Risks and related risk management of the organization • Scope and scale of compliance function activity • Regulatory requirements at the different levels of the company • Need to drive consistency (functions, issues, locations, etc.) • Perception of independence of the compliance function 	<ul style="list-style-type: none"> • Compliance function that allocates compliance resources effectively in order to manage risks appropriately • Appropriate sharing of compliance monitoring responsibilities between Compliance and the business units • Acceptance of compliance by business units • Business units embed compliance within their business units and are in compliance
Business Unit Alignment:	<ul style="list-style-type: none"> • Compliance function that is structured in a manner that is in alignment with significant business units so they can identify and address the compliance risks and meet the regulatory demands of their markets, locations and industries 	
Flexible Structure:	<ul style="list-style-type: none"> • Compliance structure that is flexible, allowing for the ability to immediately address the varying short-term needs of quickly enhancing the compliance function and addressing the compliance and regulatory requirements • Underlying compliance procedures allow the flexibility to conform to local laws and regulations 	
Compliance Organization Member Attributes:	<ul style="list-style-type: none"> • Skill sets of compliance, business unit and functional resources to effectively establish compliance culture and trust • Members should establish and manage relationships to interact and coordinate responsibilities across functions and business units 	
Complimentary Compliance Risk Management:	<ul style="list-style-type: none"> • Compliance should work collaboratively with Business Units, Internal Audit, Legal Counsel and Human Resources. Each should take on specific governance, risk and compliance responsibilities in order to help build a strong compliance structure. 	

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The Common Structures of the Compliance Function

While healthcare payers and providers typically align their compliance function and structures to the compliance model that best fits their needs, the common models include:



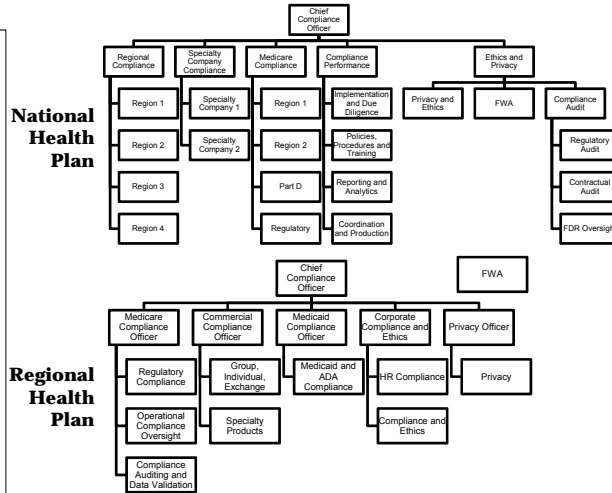
Payer compliance program structure

Key drivers:

- Types / Numbers of contracts
- Membership size
- Geographical footprint
- Operational oversight
- Expertise / Skillsets

Key considerations:

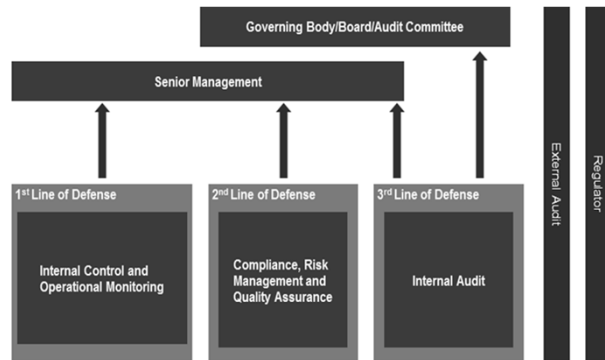
Alignment with business model
 Drives compliance accountability by the business
 Ensures effective reporting and communication upstream and downstream
 Helps standardize processes, procedures and accountabilities
 Monitors, measures and tracks compliance performance



3. The Three Lines of Defense

Definition of the Three Lines of Defense

The Three Lines of Defense distributes ownership of risks across Business Operations, Compliance and Internal Audit



Adapted from ECIIA/FERMA Guidance on the 8th EU Company Law Directive, article 41



Three Lines of Defense – 1st Line – Operations

1st line of Defense

Internal Control and Operational Monitoring

Responsible for identifying, assessing, managing, and controlling compliance risks inherent in its activities:

This principle:

- Applies across risk types (not just compliance)
- Places ultimate accountability for the management of compliance with the head of each Line of Business even if the function is delegated to a delegated entity
- Implies that the business must absorb losses resulting from compliance events
- May prompt Line of Business leaders to appoint staff within the business units to assist them in discharging their responsibilities with respect to compliance management

Acceptance of business being the 1st line of defense leads to a culture of accountability

Three Lines of Defense – 2nd Line – Compliance

2nd line of Defense

Compliance, Risk Management and Quality Assurance

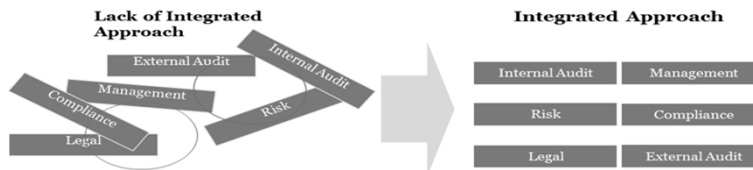
Responsible for providing compliance oversight to the business

Key responsibilities:

- Compliance risk assessment, including emerging risks
- Support with operational risk mitigation through understanding and implementation of complex regulatory requirements
- Supports organizational response to regulatory oversight
- Linkage of compliance plan to business plan, including clear understanding of strategy, business architecture and compliance profile of the business
- Compliance policies, standards, tools, methodologies and programs
- Oversight of compliance across all businesses monitoring and reporting
- Compliance aggregation and a portfolio view; reporting to management and board
- Training and venue for compliance reporting

Compliance and operational partnership

Healthcare payers and providers face a broad universe of potential risks, which require an integrated risk ownership approach between the business (i.e., operations) and the compliance function



- No single view of risk management across organization
- Differing perspectives on risk (audit vs. business, inherent vs. residual, BU vs. Group)
- Potential for duplication and gaps in risk management
- Limited Board/AC level visibility of the linkage between sources of risk management

- Collaboration between risk management functions
- Develop common view of risk to organization
- Presents to Board how key risks are being covered by risk management functions
- **This is more than** developing improvements in risk-based internal auditing

3. Spotlight: Compliance Monitoring

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Compliance Monitoring

Organizations must have ongoing procedures ingrained in daily operations to routinely measure operational performance against key regulatory requirements

Sample Questions for Consideration

- In what ways does the organization use monitoring to track and review key compliance program activities (e.g., corrective action plans, vendor compliance, warning letters, non-compliance, regulator sanctions)?
- When the organization implements new or updated regulatory requirements, including monitoring and quality control measures, how does it confirm appropriate and timely implementation?
- How are monitoring results disseminated to appropriate stakeholders, including the Board, compliance committee, senior leadership and business unit leadership?

Data Elements and Metrics

- Quantitative compliance monitoring tools (e.g. scorecards, dashboard reports, KPIs)
- Operational monitoring tools which report on key aspects of regulated operations (e.g., reporting that is tracked and compared over time)
- Business unit-specific compliance monitoring reports (e.g., business unit scorecards or dashboards including metrics such as regulatory turn around times or appropriate handling/classification)

Sample Design Attributes

- Compliance monitoring results are evaluated, aggregated and reported to the compliance officer, Board, senior leadership, compliance committee and business unit leadership
- Monitoring results are continuously used to remediate and improve organizational strategy and compliance risk mitigation
- Monitoring activities are continuously tracked, trended and supported by necessary cross-functional stakeholders

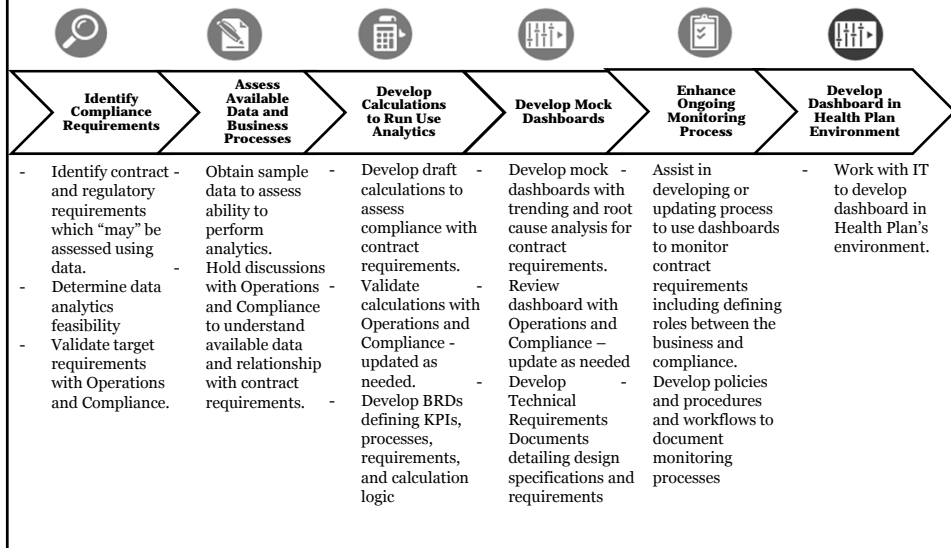
Q: Please indicate what tools your organization uses in evaluating its compliance program?	
Hotline/helpline metrics	92%
Compliance audit results	78%
Risk assessment results	76%
Training completion rates	68%
Customer & other third party feedback/complaints (not reported through hotline/helpline)	64%
Employee disclosures (e.g. conflicts of interest and gift reporting)	54%

Examples of areas for compliance monitoring

Below are examples of metrics for which operational compliance monitoring routinely takes place.

Business Area	Relevant Examples
	<i>Note: Thresholds set for KPI metrics are based on regulatory requirement/ expectations and/or plan sponsor internal standards of operations</i>
Appeals & Grievances	<ul style="list-style-type: none"> - Standard Grievances Resolution Turnaround Time (TAT): 95% within 30 calendar days - Expedited Reconsideration Resolution TAT: 95% within 72 hours - Claims Reconsideration IRE Overturn Effectuation: 95% within 30 calendar days
Claims	<ul style="list-style-type: none"> - Payment of Non-Contracted Providers Clean Claims TAT: 95% within 30 calendar days - Payment of Contracted Providers Claims TAT: 95% within 60 calendar days from date of receipt - Denial of Non-Contracted, Non-Clean Claims TAT: 95% within 60 days
Customer Service	<ul style="list-style-type: none"> - Customer Call Center Average Hold Time: Not to exceed 2 minutes after IVR or touch tone response and before reaching a live person - Customer Call Center Average Speed of Answer: 80% within 30 seconds - Customer Call Center Disconnect Rate: Not to exceed 5%
Enrollment	<ul style="list-style-type: none"> - Acknowledgement of Receipt of Complete Enrollment Application: 95% within 10 calendar days of receipt - Confirmation of Enrollment Sent to Member: 95% within 10 calendar days of TRR receipt - Notice of CMS Rejection of Enrollment Sent to Enrollee: 95% within 10 calendar days of TRR receipt
Sales	<ul style="list-style-type: none"> - Resolution of Sales Allegations: 95% completed within in 30 days - Notify CMS of Marketing Events: 90% within 7 calendar days prior to the event's scheduled date, or prior to advertising the event, whichever is earlier - Scope of Appointment Signed Prior to Appointment: 95% completed 1 business day before appointment
Utilization Management	<ul style="list-style-type: none"> - Pre-Service Auth Routine Notice of Extension: 95% within 14 calendar days - Pre-Service Auth Urgent Resolution TAT (Extended): 95% within 3 calendar days of oral notice + up to 14-day extension - Expedited Drug Benefit Coverage Determination TAT: 95% within 24 hours

Developing data-enabled monitoring



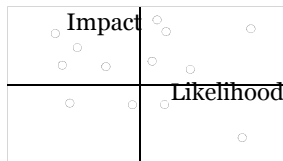
Create risk-based approach for auditing and monitoring compliance performance

Program Component

Audit/Monitoring Plan

Develop a work plan and processes to audit routine operational and compliance performance

Utilize an Impact vs. Likelihood analysis to understand high risk functions



Leading Practice

- Formalize an annual, risk-based auditing plan based on the sponsor's annual compliance risk assessment, risk appetite, resourcing, and coordination with the business
- Prioritize tasks based on risk, including:
 - Potential beneficiary impact (scale, scope, severity, volume, type of delegated activity)
 - Historical operational, compliance, and contractual performance
 - Enforcement trends related to the function
- Determine the type and intensity of audit based on the risk and prioritization assessment

What is a Risk-based approach for auditing and monitoring compliance performance?

Program Component

Routine Monitoring

Plans should execute administrative activities to detect instances of non-compliance, trend performance, and confirm that instances of non-compliance have been effectively remediated.

Leading Practice

- Develop measurable metrics and key performance indicators (KPIs) based on delegated activities
 - Compliance metrics including: training, code of conduct, excluded entities/persons screening
 - Operational metrics such as: claims accuracy and timeliness, appeals timeliness, number of grievances, transition fill accuracy and timeliness, authorization timeliness
- Clearly define reporting process including ownership, due dates and clear accountability
- Trend and regularly report KPIs
- Incorporate metrics / KPIs of FDRs into Compliance dashboards presented to organization's leadership, Compliance Committee(s) and the Board of Directors
- Include all operational data (including FDR data) within enterprise data warehouses to streamline reporting capabilities

Implementation of a transparent and effective reporting and response to identified issues

Leading Practice

Program Component

Detected Offense Reporting and Response

Compliance issues are identified and reported timely and internal stakeholders are provided with information to adequately understand the severity and root cause of the issue. Stakeholders are accountable to track the FDR's remediation of identified issues.

- Document escalation protocol with criteria for internal and external response pathways
 - Identify actions to be taken with FDRs in response to instances of non-compliance
 - Align actions with organization's code of conduct and vendor contracts
 - Include criteria, protocols, and process for vendor de-delegation and termination
 - Identify internal stakeholders, including committees and the Board of Directors, for each stage of the escalation process
- Align the escalation reporting process with established Compliance governance
- Incorporate FDR deficiencies identification, tracking and remediation in existing corrective action processes, maintain corrective action plans by FDR, and include remediation confirmation as part of closing out corrective actions

5. Achilles Heel? FDR Oversight!

Why is an FDR oversight program important?

- **Compliance with regulator expectations:** CMS, for example, holds plan sponsors accountable for the compliance of its FDRs with Medicare regulations and requirements.
- **Vendor Management:** Enable improved vendor performance management through compliance oversight processes.
- **Access to quality of care:** Increased coordination between sponsor and FDR may enable improved access to care and better member retention.
- **5 star rating:** Cooperation between the sponsor and FDR may result in improvements to care delivery and data collection.

Example business functions delegated to FDRs

- Pharmacy Benefit Manager
- Sales
- Claims
- Authorizations and Referrals
- Enrollment
- Member materials and communication
- Credentialing
- Medical Management
- Disease Management
- Behavioral Health
- Customer Service
- Fulfillment

Example framework for an effective FDR oversight program

Foundation	Core Regulator Expectations				
<p>Governance</p> <ul style="list-style-type: none"> - Operational Ownership - Operational Committees - Board Oversight 	Standards of Conduct, Disciplinary Standards and Policies and Procedures	Training and Education	Oversight of Delegated Activities (Operational Performance)	Oversight of Compliance and Fraud, Waste and Abuse	Issue Remediation and Verification
<p>Program Components</p> <ul style="list-style-type: none"> - Identification of FDRs - Communication of Expectations - Management of Compliance - Routine Monitoring - Risk-based Auditing - Detected Offense Reporting and Response 					
<p>Oversight</p> <ul style="list-style-type: none"> - Operational reporting - Key risks - Controls effectiveness - Compliance Key Performance Indicators - Representation to members /regulators that FDR=Plan 	Related Processes				
	Meetings	Data	Performance	Other	

Key questions on FDRs and how compliance and business should oversee

I. Policies and Procedures		Internal	External	Other
1	Written Code of Conduct			
2	Code of Ethics			
3	Code of Ethics			
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Questions to consider:

- How are you comfortable that your FDRs are meeting all of your regulators' (including CMS') expectations?
- Is your risk-based audit plan effective?
- What is the involvement of the corollary business unit in overseeing FDR performance?
- Is the active monitoring and training you're performing over or providing to your FDRs improving FDRs performance?
- Are you and/or the corollary business unit receiving accurate and valid performance reporting including compliance KPIs?
- Have you received any CTMs or grievances pertaining to FDR activities?

5. Questions

Thank you!

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