

Compliance 2020: Compliance and business roles in today's complex regulatory environment

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Presenters



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Session objectives

Trends and developments	<ul style="list-style-type: none">Review the key developments and trends across the healthcare industry related to the evolving role of compliance and the role of business units
Compliance's role in regulatory requirements	<ul style="list-style-type: none">Discuss how compliance has helped define the role of meeting regulatory requirements
Compliance performance and embedded compliance structures	Discuss: <ul style="list-style-type: none">Embedded compliance supportPerformance/program support teams & unitsHow risk ownership is driving the role of business units

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Compliance trends and developments

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Compliance trends and developments

Digital initiatives shift talent needs, and the tools & workforce of the future for compliance and ethics programs



Technology-enabled services bring new perspectives to the regulatory compliance and ethical risks.



The compliance workforce of the future is one supported by AI.



Increased automation for routine compliance tasks.



Technology-enabled services bring new perspectives to the regulatory compliance and ethical risks.



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Compliance trends and developments

Compliance and ethics programs are making significant headway in their digital fitness. Key attributes include:

- Organizations with more-digitally-fit compliance programs are seeing greater benefits from the advent of digital initiatives.
- Such positive results include more-effective management of transformation risk and more payoff than expected against planned outcomes such as improved customer experience, risk mitigation and revenue growth.
- Compliance executives can advise on digital transformation without stalling the speed at which the business has to act. Indeed, by staying ahead of regulatory change, compliance and ethics programs can help their organizations meet their digital goals.



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Compliance trends and developments

Culture has a long history of being recognized as a critical component to operating in compliance with laws and regulation, and continues to trend as a continuing expectation

2019 guidance

The DOJ updated guidance for prosecutors to consider various aspects of the compliance program in determining whether to prosecute corporations/individuals and/or enter into deferred prosecution agreements. It contains critical aspects involving the culture of compliance, and further solidifies the importance of culture:

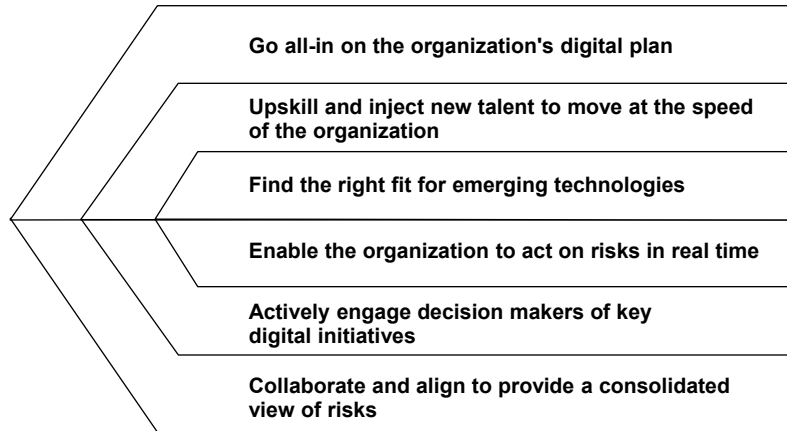
- Determine “whether the corporation’s employees are adequately informed about the compliance program and are convinced of the corporation’s commitment to it.” (criteria for an effective compliance program include “[t]he company’s culture of compliance, including awareness among employees that any criminal conduct, including the conduct underlying the investigation, will not be tolerated”).
- Beyond compliance structures, policies, and procedures, **it is important for a company to create and foster a culture of ethics and compliance with the law.** The effectiveness of a compliance program requires a high-level commitment by company leadership to implement a culture of compliance from the top.
- Culture of Compliance – How often and how does the company **measure its culture of compliance? Does the company seek input from all levels of employees** to determine whether they perceive senior and middle management’s commitment to compliance? What steps has the company taken in response to its measurement of the compliance culture?
- Prosecutors should also assess whether the company has established policies and **procedures that incorporate the culture of compliance into its day-to-day operations.**

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Compliance trends and developments

Digitally fit compliance programs include an eye toward the workforce of the future and greater use of technology tools for compliance risk management

Habits of digitally fit compliance programs



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Compliance's role in regulatory requirements

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Compliance's role in regulatory requirements

As the pace of change continues to accelerate, compliance and ethics organizations have to become strategic partners of senior executives and understand the risk new and changing requirements entail

How? By moving themselves to the forefront to:

- Anticipate forthcoming regulatory changes and make plans for how to adapt to them
- Identify regulatory compliance risk early and proactively to quickly respond to possible issues
- Avoid delays in timely implementation by early planning



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Compliance's role in regulatory requirements

Anticipate regulatory changes and plan for how to adapt

Skill sets: having in place the skills and competencies for strategically advising stakeholders on constantly evolving regulatory-compliance risks

Rapid change management: adapting compliance processes, tools, and services to help the organization anticipate and respond to regulatory change at the pace required to maintain compliance

- Navigate the regulatory risk and compliance implications throughout the organization
- Be involved early in such initiatives at the "idea" stage of innovation in order to provide perspective on the ethical and regulatory considerations that could influence program feasibility and design

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Compliance's role in regulatory requirements

Key regulatory change management activities are defined across Compliance as owners and monitoring of areas owned by other functions that support regulatory change management

		Organizational adoption and accountability
	Transparency and improved performance monitoring	Tailored training to enable program success
Defined, risk-based approach	Greater visibility into the full scope of regulatory change and regulatory change accountabilities	Measurement, metrics, and reporting to drive accountability and program adherence
Consistent approach to intake, assess for impact, and implement on regulatory changes across risk areas (e.g., information security, privacy, operational)	Management activities and monitoring that improve performance and enable cross functional and department collaboration	Processes for timely escalation of significant issues to senior management
Frameworks and approach that balances cost, speed and risk management		



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Compliance's role in regulatory requirements

Using digital fitness to evolve and enhance regulatory change management support through various technology capabilities

	Enterprise view into the need for compliance inputs supported by real-time process workflows
	<ul style="list-style-type: none"> • Input capabilities are available to various risk function responsible for monitoring potential new or updated regulatory requirements • A holistic universe and tracking of regulatory changes is available, tracked, and reported on through technology systems
	Technology accelerators
	<p>Systems and process workflows are built with specific accelerators that assist in efficiently managing regulatory changes. These accelerators include, but are not limited to:</p> <ul style="list-style-type: none"> • Project plans and test scripts • Design templates and data dictionary • Dashboards and report templates • Example roadmaps and return on investment models/total cost ownership analysis • Training plans and material • Change management metrics

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Compliance performance and embedded compliance structures

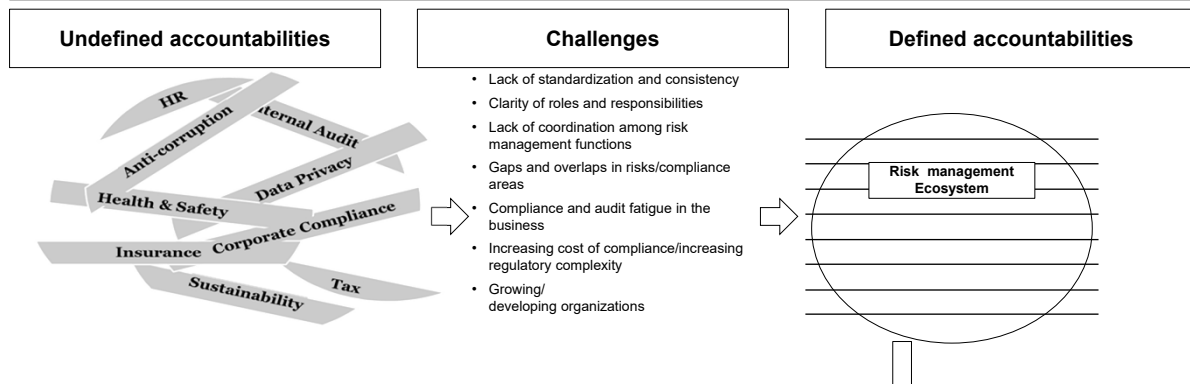
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Compliance performance and embedded compliance structures

Organizations are moving toward mature alignment of functions, risks, and compliance accountabilities

Aligning functions under a clear risk management and defined approach to compliance accountabilities across functions



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Compliance performance and embedded compliance structures

A strong second line of defence is supported by ongoing enhancements to compliance processes and integration with risk management functions and reporting

	Traditional / basic elements	Moderate	Advanced view
Role of Second Line of Defense	<ul style="list-style-type: none"> Dedicated activities and functions organized around high risk areas of the organization Activities and priorities driven based on individual mandate 	<ul style="list-style-type: none"> Independent & decentralized operating risk and compliance functions focused on enabling business performance Greater collaboration among various 2nd LOD functions and activities 	<ul style="list-style-type: none"> Strategic asset to senior management to enhance business performance while providing effective oversight of risk management and compliance activities
Responsibilities	<ul style="list-style-type: none"> Individual reporting to senior management and the Board Risk and compliance efforts driven based on entity goals and risk priorities Coordination with the 1st line of defense 	<ul style="list-style-type: none"> Integrated and consistent risk reporting to Board and management Common risk taxonomy based on integrated risk framework Collaboration in risk assessment, execution and reporting through risk committees and/or corporate compliance group Coordination with the 3rd line of defense (i.e. IA) 	<ul style="list-style-type: none"> Integrated, real-time risk reporting to Board and management through risk dashboard Continuous monitoring and/or exception based reporting on high risk areas and key 'economic value' drivers Common leverage models to enhance ROI on people, process and technology resources Structured reliance model by 3rd line of defense
Value	<ul style="list-style-type: none"> Identification of risk exposures and mitigation measures 	<ul style="list-style-type: none"> Identification of gaps and overlaps in risk management and compliance activities Enhanced business performance 	<ul style="list-style-type: none"> Significant economic, social and brand value creation through effectiveness and efficiencies in risk management and compliance activities

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Compliance performance and embedded compliance structures

Varying approaches, and level of implementation is seen across the healthcare industry for compliance accountability

	Potential Pros	Potential Cons
Centralized compliance	<ul style="list-style-type: none"> Greater independence, efficiency and clear accountability Increased understanding and recognition by stakeholders of compliance resources, roles, and responsibilities Can drive a singular compliance framework 	<ul style="list-style-type: none"> Accountable for potentially new and unfamiliar functional areas/business units Risk of the business abdicating all compliance responsibilities (i.e., "that's the role of the compliance department")
Decentralized compliance	<ul style="list-style-type: none"> Business is clearly accountable for operational compliance Compliance understands how the business operates as it is embedded in the business, or has resources with embedded compliance responsibilities established within operations Specialization and pointed subject matter knowledge for each product/market 	<ul style="list-style-type: none"> Siloed approach and much more expensive from a resourcing standpoint Lack of consolidated compliance reporting to senior management and the Board Potential for loss of independence/pressure to not raise compliance issues if compliance is part of the business
Hybrid compliance	<ul style="list-style-type: none"> Potential for more cross-functional collaboration Consolidated compliance reporting to senior management and the Board Supports the management of all compliance risk since compliance functions are embedded in both the business and the Compliance Department 	<ul style="list-style-type: none"> Potentially more resource intensive than centralized model Potential redundancy and confusion on the delineation of roles and responsibilities of different compliance functions (business based compliance v. Corporate Compliance) if not clearly communicated or understood by the organization

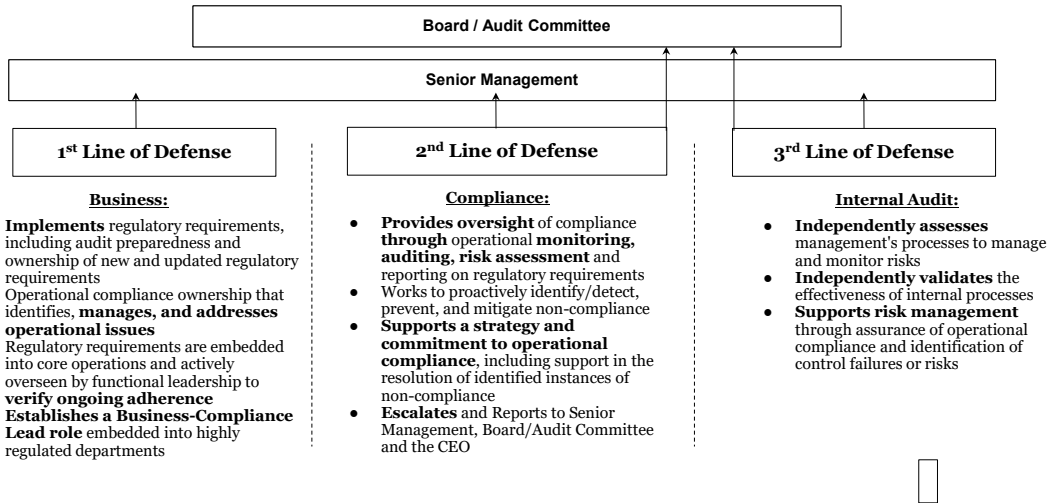
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Compliance performance and embedded compliance structures

Harvard Pilgrim Health Care's approach to compliance risk management



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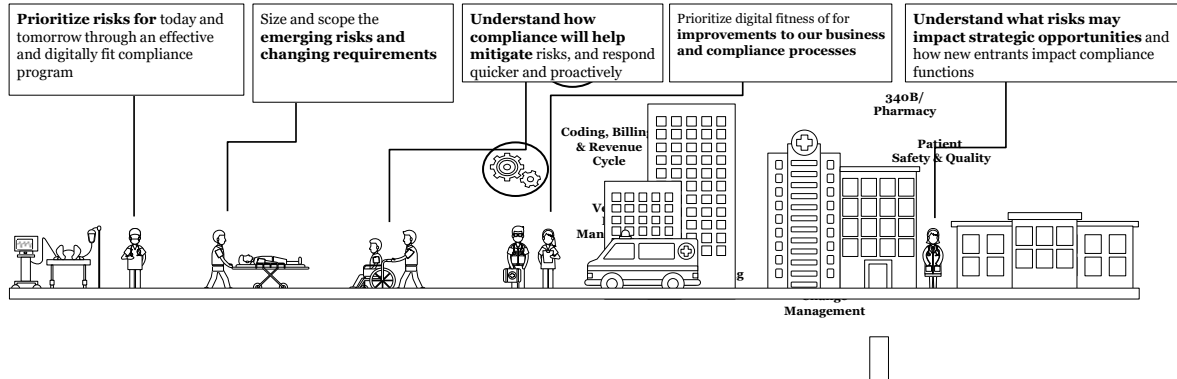
Key takeaways & Q&A

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Compliance performance - Bringing it all together

Cultural compliance, digital fitness, and rapid regulatory change management helps provide effective risk prioritization and alignment of key activities for Compliance programs



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