

# *New Entrants: Charting the Health Industry's Risk and Regulatory Landscape*

Where Risk Meets Opportunity

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The new health economy is bringing change and new entrants from diverse industries are stepping into revolutionize care. Conscious of the risk endemic to the market, successful companies are using risk management to gain a competitive advantage, employing a proactive approach to industry complexities that isolates risks and allows them to move forward with a solid compliance plan of action.

As traditional healthcare players, such as hospitals, healthcare systems, and pharmaceutical companies, adapt to an emerging, value-driven landscape, new entrants are entering the scene from a multitude of industries. Retailers, technology companies, telecommunications businesses and consumer products entities are offering up new products and services designed to meet government and consumer pressure for efficient, lower cost and convenient healthcare options.

Alternate treatment centers are springing up in retail markets, home testing of common ailments<sup>1</sup> are on the horizon and wearable devices that monitor functions such as heart rate, hydration levels and sleep patterns are sparking the interest of home health and wellness consumers.<sup>2</sup> But successful new entrants entering the healthcare space are thinking about more than the prospect of shaping an industry. They are learning about the myriad of regulations and codes that may impact their daily business activities and referencing U.S. federal and industry association guidelines for guidance on establishing effective compliance programs. These new entrants have learned that a proactive approach to identifying and managing risk is more than a prescription for avoiding and mitigating events. By limiting risks, organizations gain long-term sustainability and market place credibility that extends to raising funds or seeking buyers.

### ***Mitigating the far-reaching effects of risk***

The healthcare industry is evolving before our eyes. What holds true today could easily change tomorrow, making routine risk assessments and prioritization a vital ongoing process. While many new entrants are familiar with the concept of the risk and the regulatory landscape in their current lines of business, the healthcare arena presents unfamiliar challenges and obstacles. Across the value chain,

from research and development through manufacturing, commercial and medical processes, organizations are exposed to risk from a variety of sources. Regulation alone encompasses a vast universe that includes FDA, anti-kickback and other laws that affect everything from product development to interactions with healthcare professionals as well as the protection of consumers and the privacy of patient health information, to name a few.

Before a new entrant can seize opportunity in the new market, they first need to understand health industry regulations and risk factors. A struggle many new entrants face is how to balance these new risks against the needs of the business that may not be focused on the healthcare environment.

This is accomplished as new entrants adopt a proactive strategy that includes:

- Selecting the most appropriate operating structure
- Identifying and prioritizing the risk universe
- Taking time early in the pre-commercialization process to establish a risk management plan, including the organizational design required to manage acceptable levels of risk
- Building a roadmap toward an incorporated compliance function capable of supporting critical decision making in the early stages and beyond

Following PwC's Integrated Framework Approach, new entrants can more easily navigate industry complexities and build an effective compliance program.

<sup>1</sup> PwC Health Research Institute, "Healthcare's New Entrants: Who Will be the Industry's Amazon.com?," PwC, 2014.

<sup>2</sup> PwC Health Research Institute, "Health Wearables, Early Days," PwC, 2014. [www.pwc.com/hri](http://www.pwc.com/hri)

## Adopting PwC's 4-Phase Approach to Developing a Compliance Program

Developing a compliance program in the complex healthcare market can easily be accomplished with the help of PwC and a 4-phase approach:

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## Where are you now? Identifying the operating model

The first step in ensuring an entity can identify, isolate and manage risk, is by evaluating and selecting the appropriate operating structure – either an integrated, hybrid, stand-alone, or partnership model.

An integrated model expands on current infrastructure, processes and systems to serve both new and existing compliance service capabilities. Healthcare risk concerns are incorporated into broader Enterprise Risk Management. This makes sense for some entities, especially where health products and services align well with existing offerings and geographic markets, but this model also exposes an organization to the greatest potential risks.

Similarly, a hybrid operating model delivers some of the same cost saving advantages by sharing the processes and systems that provide the greatest benefit to the organization as a whole, but minimizes more of the exposure by dedicating resources to healthcare compliance and

isolating the areas of the business prone to the highest risk. Meanwhile, stand-alone operating models provide the most protection to the organization by centralizing risk in a separate department, but are not as cost saving due to some operational redundancies.

## Where do you want to go? Making risk-savvy decisions

Next, a company needs to determine how it plans to manage risk decisions. A new entrant's ability to survive the healthcare ecosystem's highly regulated environment is dependent on how effectively it can incorporate, embrace, and manage the appropriate risks as part of organizational strategies, operations and processes.

How risk is shared and absorbed across business units is one factor in determining the amount of risk an entity can assume or how to best mitigate those risks. Appetites are generally quite high for new competitors entering a space, whereas a long-established organization may be less inclined to indulge in the same risk patterns. Making risk savvy decisions requires a view of the universe as a whole and the ability to distill down to the applicable risk factors. Successful organizations entering the healthcare space incorporate legal and regulatory counsel responsibilities as part of the pre-commercialization and decision making process. By pulling forward internal knowledge and expertise across the business, new entrants gain a complete view of the risk landscape, assessing organizational activities and commercialization markets to then isolate the most probable risk factors. By identifying the areas of impact early, new entrants can plan for challenges that could otherwise prohibit or cut short entry.

Another path to successfully managing risk is through partnerships with incumbent healthcare organizations. Depending on their market strategy and product development stage, marketing or collaborating with traditional healthcare companies or industry trade associations, such as the Advanced Medical Technology Association (“AdvaMed”), could help navigate some of the complexities of the market.

## How can you manage the risk you decide to take? Building the compliance structure

Maintaining an effective compliance program protects brand reputation and value by enabling crisis prevention, management and remediation. Given the dynamic state of the health industry, and new risks related to the new health economy, organizations typically follow specific guidelines to establish a functioning structure that meets both organizational needs and regulatory requirements. This includes the development of policies and procedures that help manage risk as well as the inclusion of effective controls and internal business unit self-monitoring to evaluate how the risk model is functioning and to identify emerging risks as the landscape continues to change.

As new entrants take stock of the pre-commercialization landscape, they can consider the scope and shape of their compliance function by determining:

- The span of control
- The necessary resource requirements
- Lines of reporting
- Resource model as well as necessary new skill sets
- The formation of governance committees

In addition, new entrants can become acquainted with healthcare industry better practices related to compliance. To bring organizational concerns and critical issues to the forefront earlier in the decision process, established healthcare entities are elevating the role of the Chief Compliance Officer (CCO), recognizing the necessity for a CCO who reports directly to the board of directors or audit committee.<sup>3</sup> Managing risk requires a full time professional at the helm, one in charge of a standalone department, budget and resources. This growing trend underscores the emphasis the healthcare industry places on the compliance

environment. By shifting the focus from the legal arena and including compliance officers in strategic decision-making, organizations effectively enable the CCO's ability to escalate issues and better embed compliance-related processes throughout the organization.

Also of primary concern to compliance-oriented organizations is the resource model. Many chief compliance officers are expanding their standard team definitions beyond legal experts to include professionals with proficiency in data analytics or with clinical, technical or business backgrounds.<sup>4</sup> Drawing on this rich and varied experience, the compliance function can generate more timely business insights, improve decision-making across the organization and establish protocols to prevent serious mishaps, particularly in the early planning phases of product innovation.

The formation of a separate compliance committee is another element of the compliance structure that is being employed in healthcare organizations. When fully supported by and empowered with talented and knowledgeable individuals from across the company, the formation of a committee sends a clear message on the organization's commitment to compliance. Equally as important, a compliance committee stands as a line of defense. By providing senior decision makers with the right information to navigate legal obligations and reporting on overall compliance, an organization also empowers those on the front lines of everyday operations to understand and manage the issues and risks that impact their business activities.

<sup>3</sup> "PwC State of Compliance 2014, Healthcare Provider Industry Brief" <http://www.pwc.com/us/en/risk-management/state-of-compliance-survey/assets/pwc-soc-provider.pdf>.

<sup>4</sup> "PwC State of Compliance 2014, Healthcare Provider Industry Brief" <http://www.pwc.com/us/en/risk-management/state-of-compliance-survey/assets/pwc-soc-provider.pdf>.

## How will you get there? Developing the risk management plan

Capitalizing on the emerging opportunities in the healthcare industry requires substantial risk consideration and a prioritized road map that guides the creation of the compliance structure. An effective compliance program is embedded in the organization's operations and has buy-in from the top. Senior leadership sets the tone for the rest of the organization by supporting the formation of a compliance committee and by demonstrating a personal and organizational commitment to compliance. This includes the development of policies and procedures that manage risk, the inclusion of effective communication to ensure the policies and procedures are easily understood, and periodic formal assessments to evaluate how the risk model is functioning and to identify emerging risks as the landscape continues to change. Additionally, performance metrics should guide employees toward the goals and objectives of the compliance program, while performance incentives award ethical behavior.

## Risk management as a competitive advantage

Recognizing the complex nature of the industry and the variety of new entities now entering or inhabiting the space, there is no "one size fits all" compliance program. As new entrants join the emerging new health economy, they follow a twisting road marked by changing guideposts. The organizations that have an ability to understand those changes, and then assess and manage the overall risk to their business model, will be the ones that come out on top. Risk management becomes a competitive advantage when it maximizes efficiency and minimizes exposure, resulting in long-term sustainability and market place credibility.

To gain an edge in a competitive market, new entrants should follow leading industry practices when building a compliance structure and consider the following:

- Turning risk management to a competitive advantage will require new entrants to obtain maximum value from the operation. Integrating common compliance

methods, tools and practices across the business will ensure consistent communication and reporting in a cost effective manner.

- Establishing a formal process for prioritizing risks, and then aligning mitigation, monitoring and control functions by priorities, is also key to obtaining valuable insights while maintaining an efficient operation.
- Successful healthcare companies are following emerging better practice methods, escalating the role of the CCO to one who reports directly to the audit committee or board of directors. By doing so, they demonstrate agile and supportive compliance programs. Focused on recognizing critical issues early in the decision making process, they also support the formation of compliance teams and committees, incorporating members from varied backgrounds and expertise.
- Adopting a culture of compliance is critical to program success, including continuously monitoring the risk universe for emerging factors and evaluating the impact on operations, strategy, resources and the organization as a whole. This is an area where analytics can help by making sense of historic trends and monitoring current activities, while proactively identifying key risk indicators.

The most effective and responsive compliance programs are embedded in operations and have a seat at the table when discussing operational and strategic planning. This provides the organization with the opportunity to identify risk early on and develop reactive strategies for mitigating risk with all stakeholder input. As new entrants plot their course along the new healthcare path, early risk consideration, planning and strategy adoption will do more than prepare them for the complicated challenges of the industry. It will enable a more sustainable, effective and competitive organization capable of leading the way for all new entrants entering the new health economy.

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