

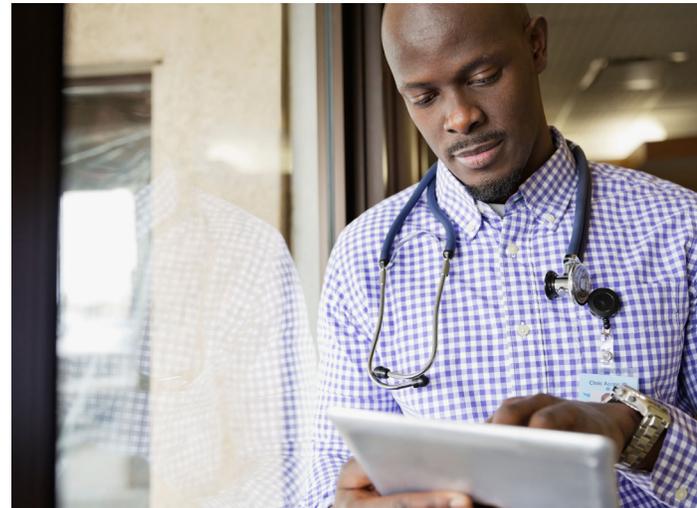
Health Insurance Exchange: How health plans can thrive in a new regulatory model

In its early stage off the page and into action, the health insurance exchange (HIX) market has witnessed significant regulatory changes. When health insurance plans look back on that time, however, they will probably find that the Centers for Medicare and Medicaid Services (CMS), which oversee HIX, and state insurance regulators spent it playing an unusual—and temporary—role.

The regulatory changes will keep coming, but the way regulators approach them is likely to revert to “normal.” That means more scrutiny and a more complex compliance task for plans that have set out to capture the HIX business. Together, these trends define a new set of circumstances that plans need to recognize and adapt to. If they don’t, they face the risk of significant fallout, including government sanctions, higher compliance costs, potential reputational harm and resultant market loss.

Organizations that make robust plans and take proactive measures to build next-era compliance frameworks can avoid that fate—and help blunt the impact of remaining uncertainties, such as the outcome of court challenges to the relationship between federal and state-run exchanges. If they don’t want to spend the future reacting, plans need to spend this year getting ahead of likely changes. Only with compliance sewn up tight can they move ahead with the growth and development that HIX promises.

This article will describe a new reality confronting the health plan industry and the anticipated future state the “new normal” will usher in. In addition to an examination of the perspectives that have emerged from early interactions with CMS and plans, it will also consider the key steps an organization should consider when launching an effective and broad HIX compliance program and the methodologies it should implement to manage and measure that program’s performance.



The new way is here to stay...

The Affordable Care Act (ACA) isn’t done rolling out yet. Barring further delays, regulations will continue to roll out at least into 2018. But the large-scale change that ACA represents has already arrived: the end of the old normal.

The new normal has shifted the industry away from the siloed operating spaces it has long occupied. Instead, compliance now requires an integrated model that spans an entire enterprise. Compliance can no longer be a “corner of the desk” task.

The risk of financial penalties, coupled with continued uncertainty over the regulations, makes it critical for health plans to build adaptable new capabilities now—capabilities that help institutionalize heightened management of business controls, improved standardization, and alignment of compliance to business drivers and goals.

The key to achieving effectiveness is focus—in compliance, risk management, and good governance. The smooth interaction of these three areas will act as a platform from which health plans will have an easier time managing compliance risk across their exchange-related operations.

Health plans should make critical and bold investments to identify the financial and talent resources they will need to build that strong foundation. Choosing those investments will be a process of great deliberation. Yet one of the first judgment calls an organization has to make isn't about process—it's about culture.

The plan to create and follow a new compliance model will succeed or fail on the backs of the people who have to understand it, internalize it, and live it each day. Is senior management committed? Are the current personnel up to that task? This isn't entirely a conscious decision: A workforce is like a body that will either accept or reject a new graft. If an organization reaches the conclusion that its people are ready to embrace change, then it can proceed directly to operational matters. But if an organization believes its culture is resistant to change, then it will have to take steps to change the culture first. Culture change is a complex process on its own, and it doesn't happen overnight—so it's clear this first-stage determination will have a large impact on the overall pace of change in the regulatory stance.

Because the regulatory environment will continue to evolve in important ways, it's natural to conclude that health plans will continue to face abundant compliance risks that will command close attention. What is less obvious—but just as important—is to recognize that regulators will be approaching their role from a perspective that is also changing.

...but the way regulators oversee it is going to change

There's one change plans will need to recognize and adapt to even though it isn't printed in any statute or code. In the future, they should expect regulators to begin playing the role of... regulators.

In the early stages of the HIX era, from interpreting legislation through the drama of the exchange rollouts, CMS and state regulators have functioned more as partners to the plans and other private-sector entities they oversee. This was natural, because everyone in the system, public and private, was working in parallel to digest the dramatic changes in the air.

But that era of "we're-all-in-this-together" will eventually run its course.

Now that the exchange regime is up and running, strong regulatory oversight is coming. The comparatively light degree of CMS and state regulatory oversight that the exchange marketplace has experienced to date should not translate into a false sense of security going forward.

The change in the wind may be unusual, but the remedy isn't: Get ahead of the game. If regulatory scrutiny over HIX operations is going to get tougher, that means it will come to resemble the way other regulatory areas have worked for years. So plans can take cues from their previous experiences with models such as Medicare Advantage and Medicare Part D, which went through similar evolutions in their time. A ramp-up in scrutiny doesn't have to be overwhelming for a plan that can draw on past lessons to beat regulators to the top of the ramp.

What practical changes will this regulatory evolution bring about? If the Part D experience is a guide, plans not only have to comply, but will also have to demonstrate that they have implemented a compliant systematic approach. CMS may turn to a more test-and-outcome-based approach to oversight and use more sophisticated methods. This is where time and resource investments focused on developing and maintaining compliance may pay great dividends.

There is no published timetable for this anticipated change in attitude. Nor is there a need to reinvent the wheel in areas of basic compliance infrastructure. As with the internal challenges that come with HIX compliance, this external factor depends largely on culture. Plans should find ways to cast their regulatory relationships in ways that are collaborative rather than confrontational—and anticipatory rather than reactive.

This approach to compliance will require a dedicated cohort of top talent to guide organizations through the process. And senior leadership should make it a top priority to define and implement a set of guiding principles for an effective compliance program. The completion of an effective program launch, based off of a strong organizational framework for compliance readiness, can propel plans forward into a phase of growth and development no matter how quickly the environment changes or how dramatically its regulators' perspectives may evolve.

What steps should organizations take to get started down the HIX path?

Despite the ambiguity that characterizes the present-day regulatory environment, plans can turn to a fundamental to-do list to begin setting up the capabilities and practices they'll need to make HIX work in the long run:

- **Know your federal and state requirements**
- **Assess your compliance**
- **Review your overall HIX business process**
- **Prioritize your risks and opportunities**
- **Design the future state**

Know your federal and state requirements

Knowing the requirements your organization should adhere to and documenting them in a regulatory framework is essential to maintaining ongoing compliance with ever-changing HIX regulations. This includes four key challenge areas:

Completeness. How can an organization be sure that it has captured *all* of the requirements it is required to maintain? To some degree, federal requirements can be reviewed in a single source of truth—the Code of Federal Regulations (CFR). But in working with state regulators, validating the sources of applicable regulations proves to be more difficult. Many states' legislatures have folded the requirements in their respective insurance codes.

Ambiguity. As plans saw during the rollout of Medicare Part D, sub-regulatory guidance on health insurance exchanges is only beginning to appear. The regulations as documented are written from a legal and legislative perspective, and lack the specificity of operational guidance. Some outlets such as Registration for Technical Assistance Portal (REGTAP) and the Center for Consumer Information and Insurance Oversight (CCIIO) have offered guidance, and some plans have tried to determine operational interpretations through direct dialogue with the regulators. If a health plan acts on any of these interpretations, it is vital that they be well documented as part of the compliance framework.

Volatility. The operational issues with the HIX rollout have been well publicized. In a cycle that has also become familiar, each new glitch and its patch bring a significant impact that puts health plans into an expensive scramble mode. However difficult this may be, it remains the role of a compliance function to make sure the organizational processes remain compliant with the new regulatory mandates. The struggle is staying in tune with the changes.

Organizational responsibility. The big picture is that HIX compliance is the whole organization's task. The daily reality is that each element of compliance is someone's job. Organizations can ease some of the challenges if they identify the departments and business units involved in HIX compliance and establish clear ownership by responsible personnel. This applies more critically to functions such as interpreting regulations as they are released, translating legal jargon into business requirements people can operationalize, and validating ongoing compliance. With these and other assignments in place, the next step is to connect them with good lines of communication and clear hand-offs.

Assess your compliance today

An end-to-end compliance assessment of the functions in an HIX compliance plan should include these key activities:

Document business process and sub-processes. Whether you use process flow diagrams or some other method, it is important to have a standardized approach that follows each process and sub-process from start to finish. Where are information and data coming from and going to? What handoffs traveled between departments? This is also a good way to document process controls.

Analyze and identify gaps. The organization should analyze each process against relevant regulatory requirements and identify associated gaps to assess contributing factors and root causes. Key questions in this analysis should include:

- What requirements are critical to the business process?
- Does the process as documented include the regulatory requirements? If so, what is the evidence that the artifact is embodied in the documentation?
- What controls are in place within the process to mitigate the risk of non-compliance with internal processes and regulatory requirements?

From there a team can document findings, observations, risks and recommendations. The goal is to establish traceability of compliance requirements to business processes and to set a baseline against which to monitor ongoing compliance.

Review your overall HIX business process

At this early stage in HIX operation maturity, the health plan should take the opportunity to extend its review beyond compliance only—to incorporate a full business process analysis. Tools such as process flow swim lane diagrams can help lay out the various processes and help identify inefficiencies, gaps, and other improvement opportunities. Another beneficial tool is a Supplier Inputs Process Outputs and Customers (SIPOC) assessment. In conjunction with front-line process walkthroughs and observations, tools like SIPOC analysis and swim lane diagrams can clarify the interdependencies between independent stakeholders and identify bottlenecks and inefficiencies.

Prioritize your risks and opportunities

Once you have identified gaps, how can you prioritize risks and opportunities for improvement? The first step is to define the risk universe. Document the risks, provide a detailed description of each one, and then classify it within its associated risk category. Next, conduct interview and workshop sessions where senior leaders can provide their insights into the risks associated with the HIX organization.

The results of these analyses can help the organization create a risk-prioritized heat map that allows the visualization of top risks based on potential impact, likelihood, and current levels of preparedness. Using that understanding as the basis for recommendations on how to improve business processes and mitigate risks, the organization can build a risk-based plan to remediate, monitor and report on its top risks.

Design the future state

Based on guidance from the HHS Office of Inspector General (OIG)¹, a plan's compliance program should include common overarching capabilities, each customized to the specific program areas in which regulators will conduct its compliance reviews. CMS expects these elements to be implemented, functioning, and effective. Previous experience with Medicare can help plans identify likely challenges and opportunities in making that happen.

Exchanging the status quo for ready-set-go

HIX implementation has created a dynamic, fast-evolving regulatory environment that is taking plans, providers, and consumers on a wild ride. Even five years after it became law and more than a year after the ACA became effective, the model seems to serve up regulatory changes on a weekly basis. Differences between state and federal regulations add to the drama, as does the significant diversity in the ways each state handles compliance expectations and reviews. Adapting to these compliance developments will take resource and financial investments along with new strategies, programs, processes, and technologies.

¹ 2010 Federal Sentencing Guidelines Manual, §8B2.1.Effective Compliance and Ethics Program—<http://www.uscc.gov/guidelines-manual/2010/2010-8b21>

The atmosphere is too turbulent for “wait and see” to be a winning strategy, for plans or anyone else. Instead, now is the time for plans to look ahead at the coming regulatory regime and start to launch, grow, and mature the compliance programs they will need in 2015 and beyond.

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