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Strategic Options in the Wake of COVID

Medicine's Emerging Third Eye

SPECIAL SECTION

Welcome to the Future: A Healthcare Board's Practical Guide to New Compliance Program Priorities

Healthcare Boards Are Responsible for the "G" in ESG

ADVISORS' CORNER

Embracing and Accelerating Healthcare Change Amidst COVID-19

Pause, Breathe, and Press On

These days I hold onto my loved ones a little longer and tighter than I usually do. I find myself sighing more and taking deep breaths (my "breathing tool" as my son likes to call it). The news headlines each day weigh more heavily on my conscience. But I am one of the lucky ones. I worked from home before the pandemic, and my husband transitioned to working from home easily. We have grandparents who can provide childcare. We live in a neighborhood rich with nature and open space for myriad outdoor activities. Boredom seems a small price to pay for personal safety and that of others. My struggle is in wanting to do more, to make more of a difference.

We are learning in real time, in real life, the imperative of strong leadership and what it can and can't do for us. You, readers, are leaders. Leaders in healthcare, leaders in health, leaders in this one life we have to live. I cannot understate my respect for you, your frontline workers, your physicians and nurses, whom you lead, who all sacrifice their safety and loved ones to save others every day, in the face of our nation's failure to contain, failure to control, and failure to lead. And yet you still somehow press on.

I am reminded of a passage from Tolkien's *The Fellowship of the Ring:* "I wish it need not have happened in my time," said Frodo. "So do I," said Gandalf, "and so do all who live to see such times. But that is not for them to decide. All we have to decide is what to do with the time that is given us." Press on…

Kathryn C. Peisert,
Managing Editor

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Strategic Options in the Wake of COVID

By Ryan Gish, Jeff Kilpatrick, and Mark Grube, Kaufman, Hall & Associates, LLC

As hospitals and health systems move toward a post-COVID-19 future, answers to an array of questions remain unknown. What is the path of COVID, and future surges? When will non-urgent patients return and in what numbers? How severe will the economic effects be on the community? How will consumer demands change? How will the competitive landscape change? When might the next black swan event come?

As challenging as these questions are, even more challenging is determining a strategic course for an uncertain future—a course that could, and likely should, be far different than the organization's pre-COVID path.

As they work to set a strategic course for their organizations, boards and senior leaders must make an unshackled assessment of what the new landscape could look like.

There is no going back to the past. As they work to set a strategic course for their organizations, boards and senior leaders must make an unshackled assessment of what the new landscape could look like. They must have true imagination in determining how each organization can help build a better future state, and be prepared to do hard and creative work in inventing that future.

The New Landscape

As tempting as it is to envision the post-COVID landscape as some recognizable permutation of the existing healthcare delivery system, leaders need to challenge themselves to see COVID as a true black swan event that could substantially change the basic environment. As one CEO told us, "We don't even remember what air travel was like before 9/11 at this point. We've just accepted it."

In the new environment, we can assume that cost-efficiency, safety, access, and preparedness will be among the new pillars of success. A brief look at just three elements of care delivery illustrate some of the potential dramatic differences.

Care models. COVID will likely change many basic aspects of traditional hospital care models. Virtual care will be a far greater element of care delivery, and consumers will expect a very high degree of convenience and sophistication in those services. A recent NRC Health survey showed that consumers are already wanting alternative care delivery options.[1] Of those surveyed, 60 percent said they are interested in phone calls, 57 percent in virtual visits, 51 percent in online patient portals, and 41 percent in text messaging, instead of attending an in-person doctor's appointment for non-emergency needs. Care sites will be segmented differently, with new concerns about space for infectious patients. A greater proportion of care and diagnostic services likely will move to outpatient sites. The typical health system ambulatory footprint will be very different. Mid-level practitioners will have expanded roles, and care rationalization and efficiency will move to new levels.

Cost structure. Hospitals are taking a financial hit of a dimension that is hard to grasp. Kaufman Hall data show that in April 2020 alone, outpatient revenue declined 50 percent, inpatient revenue fell 25 percent, and margin dropped 174 percent compared to April 2019. The American Hospital Association estimates that total hospital losses from COVID will be more than $200 billion. These staggering losses ensure that hospitals will need a very different cost structure moving forward. It is likely that the hospital workforce will be smaller, especially among administrative services. Many non-clinical employees will continue to work from home. Hospital real estate holdings will shrink. Major structure and process changes will be imperative.

Scale will be even more of a competitive differentiator. Organizations with the financial strength that scale brings will have emerged from COVID with

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Key Board Takeaways

Planning for a post-COVID future requires boards and senior leaders to explore their strategic options with imagination and invention. They must make an unshackled assessment of organizational capabilities, what the new landscape could look like, and the characteristics needed for success. Questions to ask include:

- What degree of damage have we suffered?
- What is our forecast for the next 90–120 days? The next year?
- What is the status of our clinical and non-clinical workforce?
- What options do we have for changing our cost structure?
- What is the financial and strategic position of others in our market? Our region?

1 NRC Health, *Consumer-Sentiment Data on the Coronavirus Pandemic*, May 2020.

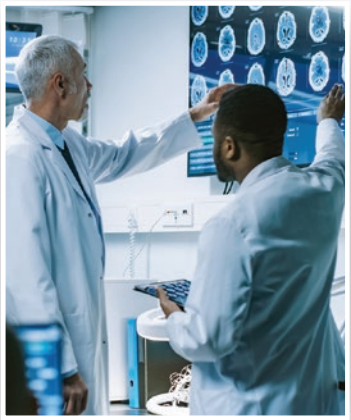
Medicine's Emerging Third Eye

By Roy Smythe, M.D., SomaLogic, Inc.

The "third eye" in Dharmic religious traditions from India, Taoism, and several other ancient religious traditions is considered to be a portal to a higher level of consciousness. Located on the forehead and connected to the mind beneath, it is capable of seeing the unseen, understanding the unknowable, and even predicting the future.

Richard Rohr, a contemporary Christian theologian and author of several books on related topics, has said, "The first eye was the eye of the flesh (thought or sight), the second was the eye of reason (meditation or reflection), and the third was the intuitive eye of true understanding (contemplation)."[1]

Great medical clinicians use Rohr's first two eyes in ways others cannot. They input large amounts of information with the first eye of sight, and the really good ones begin to collect useful data from the first moments they interact with a patient. They evaluate how the patient is sitting, standing, or lying; what they are doing with their hands; the intonation of their voice; facial expressions; how they are dressed; and so forth, in addition to the requisite history, physical exam, and the usual spate of laboratory tests, X-rays, and other diagnostic maneuvers that often follow. Then, with the second eye of reflection, they synthesize all this information into an accurate assessment and plan. Like most things in life that approximate to a "Gaussian" or bell-curve normal distribution, clinicians range from the very bad to the very good at this process, with most in the middle.



Despite the fact that some clinicians can use their first two eyes to do amazing things, they usually cannot "see the unseen" or "predict the future" as accurately as they would like, as they do not possess a "third eye." However, some newer technologies recently introduced to medicine and some just beginning to get traction in the delivery of care indeed do. The remainder of this article highlights examples of these technologies and suggests how board members might learn, inquire about, and encourage their use.

Technology Providing a "Third Eye"

Some neuroscientists believe that superior pattern recognition capability is the differentiating competency of the human brain. They suggest that humans are the dominant species, in part, because of the superior ability of their brains to store and process patterns and transfer those patterns to others.[2] While from a strictly neurological standpoint this may be true, the problem is that the number of patterns humans experience in a lifetime, and the ability to store and derive insights from incredibly large numbers of patterns, are both limited by time and our soft, fleshy processing units. However, emerging technologies are not hindered in this way, and the ability for them to experience, store, and analyze innumerable patterns is what has given them, and in turn us, access to a "third eye."

A good example of pattern recognition and processing capabilities that reach beyond those of humans is a clinical imaging approach called radiomics.[3] Radiomics involves the extraction, storage, and analysis of a number of features—such things as size, shape, texture, and density from thousands or even millions of radiographic images (plain radiographs, CT scans, MRIs, mammograms, etc.). These features are then used in creating statistical models—facilitated by the use of machine and deep learning approaches—of reproducible or predictive patterns for disease processes basically anywhere in the human body. The artificially intelligent "machine" is able to "see" patterns where humans cannot, correlate them statistically to all those it has seen before, and make recommendations for diagnoses. Some of the platforms now in use can already predict things at times more accurately than clinicians, such as whether or not a brain or kidney tumor is malignant or likely to behave more aggressively, or whether or not an invasive breast biopsy is indicated from mammogram or MRI findings.[4] Emerging uses include assisting with diagnosis of virtually all disease states that can be elucidated by expert radiographic examination, such as neurologic disorders.[5]

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Key Board Takeaways

Diagnostic technologies leveraging the use of advanced pattern recognition based on machine and deep learning will increasingly be available to augment the capabilities of physicians. These technologies will be important as more efficiency (and cost) demands are placed on healthcare delivery as it is tasked with both health promotion as well as acute care. Board members should:

- Ask their clinical and information technology leadership if these types of technologies are in use or being evaluated.
- Inquire about management leadership strategy in this area—which areas of practice will benefit most moving forward, considering the increasing need for both more efficient ways of delivering care and rendering it more accessible?
- Help management think through ways to socialize the increasing use of these approaches, as some clinicians may be resistant, and how to use them for both competitive advantage as well as to improve care.

1 Richard Rohr, "Third Eye Seeing," First Thoughts, 2019.
2 Mark P. Mattson, "Superior Pattern Processing Is the Essence of the Evolved Human Brain," *Frontiers in Neuroscience,* August 22, 2014.
3 Burak Koçak et al., "Radiomics with Artificial Intelligence: A Practical Guide for Beginners," *Diagnostic and Interventional Radiology,* November 25, 2019.
4 UW Medicine, "Study: AI Improves Radiologists' Readings of Mammograms" (press release), March 2, 2020; Ioannis Tsougos et al., "Application of Radiomics and Decision Support Systems for Breast MR Differential Diagnosis," *Hindawi,* September 23, 2018.
5 Christian Salvatore, Isabella Castiglioni, and Antonio Cerasa, "Radiomics Approach in the Neurodegenerative Brain," *Aging Clinical and Experimental Research,* August 19, 2019.

Welcome to the Future: A Healthcare Board's Practical Guide to New Compliance Program Priorities

By Anne M. Murphy, Arent Fox, LLP

Healthcare delivery has been fast-changing for decades, and the pace of this change has only accelerated in recent years and months. There are now numerous fronts of essential disruption in healthcare that, aside from strategic attention, should be incorporated into a healthcare organization's compliance program. The role of the board is to ensure that these emerging realities are adequately addressed through the compliance function, and to evaluate and provide direction to management on the key risk areas among them.

> It is always wise to look ahead, but difficult to look further than you can see.
>
> —*Winston Churchill*

At a high level, these forces of disruption for healthcare delivery include new ways of delivering care through telehealth, home health, and downsizing of traditional bricks-and-mortar-based services; the use of artificial intelligence (AI) and other cutting-edge technology; and the possibility of non-traditional partners or co-investors, including those from the private equity (PE) or venture capital (VC) sectors. Compounding this already-dynamic time, the COVID-19 era has added to these burgeoning priorities the importance of an effective public health emergency plan, the immediate need for enhanced financial stress testing, the extreme expansion of telehealth service delivery, and essential questions around workforce culture and institutional equity.

This article offers practical guidance as to how a healthcare governing board should be approaching compliance oversight in these turbulent times to ensure that it effectively addresses key forces of disruption.

Effective Board Oversight of the Compliance Program

Backdrop

Healthcare boards play a critically important role in overseeing the design and implementation of the organization's compliance program. This fiduciary duty, whether exercised primarily by one or more board committees or the board as a whole, is essential to the legal, financial, and reputational well-being of the enterprise.[1]

The focus of this article is practical, and therefore it does not offer a detailed discussion of the legal basis for a board's fiduciary duties associated with compliance oversight. However, it is important to remember that a healthcare governing board must act in good faith in exercising its oversight functions, with appropriate diligence, loyalty, and obedience to the law and the organization's mission. Among other things, this means that the board needs to have a reporting system that ensures it is adequately informed about the activities of the organization and receives timely and systematic information about compliance with applicable laws, and enables the entire organization to evaluate and take action on potentially illegal or improper activity.

Taking Action

There is a real risk of healthcare board information and functional overload in the current era. As with many governance functions, a board needs to strike the right balance so that its role is one of compliance oversight—not so focused as to supplant management and not so diffuse as to inhibit meaningful and diligent attention to risk areas.

For volunteer boards in particular, this requires a thoughtful approach that recognizes inherent time constraints but also affords directors the tools to effectively understand and evaluate complexities associated with healthcare delivery and the laws that apply. Within this framework, there should be clear means for addressing how the compliance program handles forces of disruption within healthcare delivery, an understanding of what is known and unknown at this time about each disruptive force and attendant risk, and a disciplined means for revisiting and adapting to this uncertainty on an ongoing basis.

> As we know, there are known knowns; there are things we know we know. We also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns—the ones we don't know we don't know.
>
> —*Donald Rumsfeld, Former U.S. Secretary of Defense*

From a broad process perspective, what actions should healthcare boards take to ensure continued effective compliance

Key Board Takeaways

In an era of disruption, healthcare delivery organizations are facing numerous strategic, financial, and operations challenges and opportunities. Boards should ensure that compliance oversight adapts to these forces of change. This includes:

- Taking practical steps (as described in detail in this article) that balance time and resource realities with the fiduciary obligation to have an effective compliance program.
- Assessing these governance action items in the context of current and planned innovation initiatives, including expanding services into new areas like telehealth or home health, discontinuing service lines or closing facilities, resuming elective procedures in the context of COVID-19, launching or expanding use of AI or other clinical innovations, and collaborating with non-traditional partners such as private equity firms. Moreover, there are compliance considerations associated with COVID-19 that should be addressed.
- Working closely with senior management to ensure that emerging enforcement priorities are being addressed, that sufficient resources are available at the governance and operational level, that continuous improvement is part of the compliance program, and that a culture of compliance continues to prevail throughout the enterprise.

1 *Practical Guidance for Health Care Organization Governing Boards on Compliance Oversight*, Office of Inspector General, U.S. Department of Health and Human Services; Association of Healthcare Internal Auditors; American Health Lawyers Association; and Health Care Compliance Association, 2015.

oversight in these challenging times? There is no absolute formula for this, but the following initiatives should be considered.

1. Refresh the tone at the top as being focused on compliance, even in trying times and notwithstanding enormous financial, innovation, and performance stress. A critical board role is to reinforce a culture of compliance. In times of organizational stress, as we are now seeing in the COVID-19 era, it is important for the board to signal the continuing importance of the compliance program as a top priority.

This is not to suggest that compliance should impede mission-critical actions such as securing and deploying enhanced federal and state government funding, resuming elective clinical operations, and pivoting to a more robust telehealth program on an ongoing basis. But there should be a purposeful acknowledgment by the board and senior management that these urgent actions must be implemented in a compliant manner. Even in these early days, we are seeing strong indicators that law enforcement, regulatory bodies, legislative bodies, private litigants, and the media will be scrutinizing healthcare providers' COVID-19-related actions.

2. Ask key executives to provide focused reports on regulatory and legal issues associated with the organization's emerging initiatives and circumstances. An important board responsibility is to ensure that it has an embedded program in place to be educated on compliance matters. This program should adjust to changing risk. For example, it may be appropriate for the board to receive a special report on legal and risk issues that have come to light in connection with risk-based contracting, use of social determinants of health, and enhanced quality reporting and data collection associated with value-based purchasing (VBP); the application of AI across the organization; rapid telehealth deployment; a proposed collaboration with a PE or VC firm; and/or possible closure or downsizing of a facility.

3. Consider a special board session to discuss the compliance issues emanating from COVID-19, with appropriate key executives presenting. This session could cover:

- Topics associated with clinical care during the COVID-19 peak (e.g., adequacy of PPE, workforce issues, patient safety, equitable availability of resources)
- Use of waivers and suspension of laws during the public health emergency
- Compliance with conditions of special funding
- Effectiveness of emergency preparedness plans
- Forward-looking consequences of COVID-19, such as permanent expansion of telehealth, escalating financial stress and the need for an enhanced financial monitoring plan, and the resumption of elective clinical and surgical operations

While not directly under the auspices of COVID-19, recent events strongly suggest that organizations also should be reviewing institutional equity policies, and related operations and cultural issues, from a compliance perspective.

4. Assess whether the compliance reporting structure needs to be modified to accommodate emerging compliance priorities. If primary compliance review is handled by a committee that has other responsibilities, can the committee continue to responsibly handle everything on its plate? It may be time for a committee focused exclusively on compliance.

It is also important to ensure that there is a sufficient "cross walk" between the board's compliance oversight and its quality, financial, and strategic activities. This can be achieved through overlap in committee assignments or periodic joint sessions for certain committees. An organization that participates in VBP initiatives, for example, should ensure integrated compliance oversight that involves coordination among quality assurance, finance, information technology, research, data, risk management, and legal/compliance.

Assuming the board has periodic "executive sessions" with compliance and legal leadership, assess whether these sessions are targeting emerging compliance issues, and whether executive sessions also should be held with additional leadership from human resources, quality, or institutional equity.

5. Take another look at the subject matter resources available to support the board's compliance oversight. It may be appropriate to add one or more new board or committee members with expertise in emerging areas such as population health, digital health, AI, big data, or public health. Make sure the board has direct access to all executives and clinical leadership pertinent to a given compliance area. A meaningful discussion of AI compliance, for example, needs technology, data, clinical, and medical ethics leadership, in addition to traditional compliance discussion participants.

Remember that the board can retain outside experts to advise it in certain areas. While this certainly encompasses governance, legal, and compliance guidance, it may also be the case that the board wants an independent assessment of technology, solvency, data, and risk assumption

issues that are inherently difficult for a board to fully digest.

6. Examine with senior management whether the tools used to operationalize compliance need to be updated. In order for a compliance program to be effective, it should measure relevant data, analyze metrics through scorecards or other summaries, and align leadership performance incentives with compliance priorities. These tools need to be modified periodically to reflect expanded or modified activities. For example, if the organization is expanding its telehealth, home health, and subacute operations, there should be metrics and compliance incentives corresponding to these activities. Consider also whether the organization is optimizing use of data analytics to anticipate areas at risk for compliance attention from the government or whistleblowers.

7. Revisit with key executives, including the compliance officer and the chief legal officer, ongoing reliance upon and guidance from recognized external sources, including the Federal Sentencing Guidelines, Office of Inspector General, U.S. Department of Health and Human Services (OIG) voluntary guidance materials, and corporate integrity agreements (CIAs) entered into between OIG and healthcare organizations. Ensure that case law, enforcement, and regulatory developments are being monitored and incorporated into compliance on an ongoing basis, paying particular attention to the emerging areas of operational disruption and ancillary compliance focus such as those discussed in the section below on healthcare compliance hot topics. While CIAs certainly are not binding on organizations other than those that are a party, they can provide meaningful specific guidance around risk areas and compliance techniques that may be pertinent to the enterprise.

8. Evaluate whether the organization's internal resources are well-suited to and sufficient for an effective compliance program. The compliance and legal teams should be embedded within the strategic, innovation, and operations arms of the organization, so that they are part of the decision-making and implementation process at the outset rather than an end-stage hurdle to be cleared. This requires cooperation across the organization, compliance and legal professionals who work well with others in the enterprise, and an organization-wide commitment to follow compliance and legal advice. Inquire whether the substantive skill sets within these teams are keeping up with the emerging priorities for the organization. Make sure that human resources is evaluating in a systemic way cultural issues related to compliance, including through the exit interview process.

9. Be aware of circumstances in which the organization's compliance program will need to be reconciled with, or operate alongside, the compliance programs of other organizations. Increasingly, healthcare organizations are collaborating in ways that require application of multiple respective compliance plans. This may be the case, for example, in ACO participation, in a joint venture with an outside party to commercialize intellectual property or embark upon collaborative clinical innovation, or in a corporate affiliation among health systems that is short of a full corporate consolidation. The board should discuss this with management, to understand whether there are arrangements in which this is currently the case.

Healthcare Compliance Hot Topics

As discussed above, the board of a healthcare organization should be attuned to areas of heightened compliance risk for the organization. These risk areas may be driven by investigative or litigation trends, regulatory developments, or emerging operations or strategies that, by their very nature, alter the risk profile. Highlighted below are selected trends. This is not a comprehensive list, but instead a sampling of emerging areas for compliance oversight evaluation.

Enforcement Trends

It almost goes without saying at this point that federal and state enforcement agencies have continued to focus on the healthcare sector, supplemented by federal and state False Claims Act (FCA) cases brought by private party whistleblowers on behalf of the government. In 2019 alone, the United States Department of Justice (DOJ) recovered over $2.6 billion from healthcare fraud and FCA litigation. Year over year, this dollar recovery in the healthcare sector has increased, with the majority coming from FCA-driven whistleblower cases.[2]

> If you think compliance is expensive, try non-compliance.
>
> *—Paul McNulty, Former U.S. Deputy Attorney General*

The DOJ regularly takes the opportunity to declare criminal enforcement priorities in healthcare.[3] Similarly, the OIG publicizes federal and state criminal and civil enforcement actions.[4] In any given month or week, it is likely that multiple announcements of settlement, judgement, indictment, or other action will be announced.

While it is beyond the scope of this article to discuss in comprehensive fashion these enforcement trends, healthcare governing boards should take note of the following when assessing whether its compliance oversight needs to be updated.

Sophisticated big data analytics, and AI, has become a tool used effectively by both government enforcement agencies

2 Shelby Livingston, "Feds Amassed $2.6 Billion from 2019 Healthcare Fraud Cases," *Modern Healthcare*, January 9, 2020.
3 The United States Department of Justice, "Health Care Fraud Unit" (available at www.justice.gov/criminal-fraud/health-care-fraud-unit).
4 U.S. Department of Health and Human Services, Office of Inspector General, "Enforcement Actions" (available at https://oig.hhs.gov/fraud/enforcement/index.asp).

and FCA whistleblowers. It has also altered the whistleblower landscape by increasing the prospects for outside relators using publicly available benchmarking data, as contrasted with the more traditional "disgruntled insider" relators. For healthcare organizations that are outliers in billing and reimbursement categories, and in quality and regulatory compliance metrics, this presents significant risk. While these outlier metrics may be defensible, it is important to know where these outliers exist, and to evaluate the root causes. If the deviations are defensible, the explanation should be known and documented.

Fraud enforcement tends to parallel broader healthcare trends. If healthcare delivery is expanding or innovating in a particular way, the odds of targeted robust enforcement activity is high. As a result, we have seen concerted DOJ, OIG, and state enforcement efforts in the following areas:[5]

- Addiction treatment and sober homes, with an emphasis on opioid addiction treatment
- Telehealth
- Home health and hospice
- DME, braces, and orthotics
- Compounding pharmacies
- AI use in healthcare
- PE/VC involvement in healthcare

Over the past few months, these enforcement efforts have moved more fully into telehealth and into COVID-19-related activities.[6] This almost inevitably will intensify.

Areas of regulatory or legal uncertainty present enforcement agencies and whistleblowers with opportunity. When laws shift and interpretation becomes uncertain, it creates enhanced risk for healthcare provider organizations. In the current climate, boards should understand how the organization is navigating this uncertainty, for example, in connection with:

- Proposed changes to the HHS rules governing the federal physician self-referral "Stark" and anti-kickback laws, intended to accommodate VBP.[7]
- Federal Medicaid waivers in the context of COVID-19, and state and local emergency orders and suspension of healthcare regulations.[8]
- Application of shifting federal and state regulation, and commercial payer policies, regarding telehealth service delivery, covered services, coding, and reimbursement.[9]

DOJ and OIG will continue to focus on effective corporate oversight of compliance, and board and individual accountability, in healthcare enforcement efforts. As a healthcare board updates its compliance oversight efforts, a review of key materials should include the DOJ's guidelines on evaluation of corporate compliance programs, which were updated in June 2020.[10] The purpose of the guidelines is to assist prosecutors in determining the effectiveness of a compliance program in the context of resolving an enforcement matter. These guidelines are organized around three core questions:

- Is the corporation's compliance program well designed?
- Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?
- Does the compliance program work in practice?

The guidelines provide a number of specific observations that may inform a board's assessment of its own compliance oversight effectiveness. Those relating to the importance of periodic updates and revisions, and application of continuous improvement principles to the compliance program, bear especially close review. Similarly, the updates emphasize not only the ongoing and dynamic internal improvement process essential to an effective compliance program, but also the need for more targeted training sessions and post-acquisition compliance auditing and integration.

Service Line Expansion, Resumption, and Downsizing

Healthcare delivery organizations are expanding certain service lines, downsizing or eliminating others, and resuming services that were suspended during COVID-19. In addition to the obvious strategic and financial implications of these changes, each brings the need for a compliance focus as well.

Telehealth Expansion

As indicated above, the temporary expansion of telehealth flexibility in the context of COVID-19 has accelerated a virtual care delivery trend that was already playing itself out in Medicare Advantage and other government programs. The prevailing wisdom is that this genie is now out of the bottle, and therefore some recent gains in

5 Department of Justice, Office of Public Affairs, "Federal Health Care Fraud Takedown in Northeastern U.S. Results in Charges Against 48 Individuals" (press release), September 26, 2019, and "National Health Care Fraud Takedown Results in Charges Against 601 Individuals Responsible for Over $2 Billion in Fraud Losses" (press release), June 28, 2018.

6 See, e.g., Department of Justice, Office of Public Affairs, "Medical Technology Company President Charged in Scheme to Defraud Investors and Health Care Benefit Programs in Connection with COVID-19 Testing" (press release), June 9, 2020, and "Florida Man Charged in Telemedicine Scheme" (press release), June 11, 2020.

7 U.S. Department of Health & Human Services, "HHS Proposes Stark Law and Anti-Kickback Statute Reforms to Support Value-Based and Coordinated Care" (press release), October 9, 2019.

8 CMS, "Coronavirus Waivers & Flexibilities."

9 Center for Connected Health Policy (see https://www.cchpca.org).

10 U.S. Department of Justice Criminal Division, "Evaluation of Corporate Compliance Programs," Updated June 2020 (available at www.justice.gov/criminal-fraud/page/file/937501/download); Michelle J. Shapiro, M. Scott Peeler, and Matthew H. Doyle, "DOJ Updates Corporate Compliance Guidance, Continues Focus on Risk, Reporting, and Training," Arent Fox LLP, June 4, 2020.

telehealth regulatory and commercial payer coverage may remain in place more permanently.[11]

For many healthcare delivery organizations, the transition to expanded telehealth has presented significant opportunities in recent months, and is likely to be a central part of the strategic plan moving forward. From a compliance oversight perspective, the board should understand how the organization is addressing the numerous compliance issues associated with this exciting development, including billing and covered services determinations for traditional and non-traditional telehealth modalities (including virtual check-ins, e-visits, and telephone visits), credentialing, informed consent, quality of care, and privacy/security. This discussion also should acknowledge that data mining may be applied by enforcement agencies and whistleblowers to telehealth claims and reimbursement, so possible outlier status should be anticipated and addressed. If telehealth expansion will entail significant third-party contracting, collaboration, or acquisition efforts, then targeted due diligence and compliance efforts should reflect those activities.

Care in the Home Innovation

As health systems continue to innovate in a VBP world, there is a new emphasis on care in the home. The expansion of telehealth is certainly one facet of this. But the organization also may be diversifying other home-based care options, through direct launching of licensed home health services, acquisition of or affiliation with independent home health providers, and delivery of high-acuity service through "hospital at home" initiatives. Each of these raises distinctive compliance considerations.

Home care agencies are licensed at the state level and are subject to unique Medicare/Medicaid rules.[12] In recent years, DOJ has focused on home health fraud enforcement, and the Medicare program has had active audit and enforcement action. Some of these efforts have included PE firms with ownership interests in the home health companies. Areas of focus have included improper referrals and kickback payments, medical necessity, homebound status, face-to-face service requirement, and billing and coding issues.

Home health services are subject to dramatically changed Medicare reimbursement through the Patient-Driven Groupings Model (PDGM), which became effective January 2020.[13] This model requires home health agencies to transition to a reimbursement model that has 432 case-mix adjusted payment groups, and that shifts from 60-day payment episodes to 30-day payment episodes.

For health systems that are considering entry into or expansion of home-based care, it will be important to understand the regulatory and reimbursement requirements unique to home health care. If hospital in the home acute care is being considered, this requires especially focused assessment.[14] And, if the system is considering the acquisition of an existing home health agency, due diligence should be rigorous, in light of enforcement efforts and recent regulatory changes. The Medicare "36-month rule" unique to the change of ownership of home health agencies also should be considered to confirm that it does not impede the proposed transaction.[15]

Downsizing of Services or Closure of Facilities

As was discussed at length in a recent article for The Governance Institute,[16] the board must exercise important fiduciary duties when considering downsizing of service lines or closure of facilities. Included among these duties is the responsibility to understand the legal, regulatory, and other compliance issues associated with this service or facility discontinuation. In addition to Medicare/CMS approvals, this could require Certificate of Need and facility licensure program approval and, depending on the nature of the action, could engender investigative or legal attention from the state attorney general or other elected officials.

If service line discontinuation or facility closure is precipitated by significant financial distress (or if the organization is experiencing this stress in the context of COVID-19 even without discontinuation or closure plans), the board should ensure that compliance oversight is adjusted to address this financial distress. This may suggest ongoing and targeted financial stress testing, consultation with outside legal counsel and financial advisors, and protocols to identify when the organization could be approaching the "zone of insolvency," at which point its fiduciary duties may alter.

Resumption of Elective Clinical Services

Health systems are facing the challenge and opportunity to resume elective clinical services, including surgeries and procedures, in the COVID-19 era. This resumption of services must be undertaken in a manner that is sensitive to patient safety, workforce safety, informed consent, binding requirements, and advisory guidance.[17] The board, as part of its fiduciary oversight responsibilities, should have the opportunity to review with management the particulars associated with service resumption, and should ensure that compliance oversight is part of this review. While thoughtful

11 Letter to Mitch McConnell, Majority Leader, and Charles Schumer, Minority Leader, United States Senate, June 15, 2020; American Hospital Association, "Making Telehealth Flexibilities Permanent: Legislation or Regulation?," June 2020; Casey Ross, "'I Can't Imagine Going Back': Medicare Leader Calls for Expanded Telehealth Access after COVID-19," STAT, June 9, 2020.
12 Susan Jaffe, "Home Health Care Providers Struggle With State Laws and Medicare Rules As Demand Rises," *Health Affairs*, June 2019.
13 Abt Associates and CMS, *Centers for Medicare & Medicaid Services Patient-Driven Groupings Model*.
14 Sarah Klein, "'Hospital at Home' Programs Improve Outcomes, Lower Costs But Face Resistance from Providers and Payers," The Commonwealth Fund, 2020; Robert Holly, "Hospital-at-Home Programs Ready to Play Critical Role if Coronavirus Cases Spike," *Home Health Care News*, March 16, 2020.
15 Cornell Law School, "42 CFR § 424.550—Prohibitions on the Sale or Transfer of Billing Privileges (available at www.law.cornell.edu/cfr/text/42/424.550).
16 Anne Murphy, "The Governing Board's Role in Assessing Possible Hospital Closure or Downsizing," E-Briefings, The Governance Institute, May 2020.
17 Anne Murphy, "Navigating the 'New Normal': Resuming Elective Surgeries and Procedures at Health Care Organizations," Arent Fox LLP, June 2, 2020.

documentation is always important, it is particularly important in this context.

Artificial Intelligence and Innovation

Perhaps nowhere is the future of healthcare more evident, in both its promise and its peril, than in the use of AI in clinical care and the innovations and collaborations supporting that use. The emerging deployment of AI in healthcare staggers the imagination. Whether it is the advancement of precision medicine, increased efficacy in oncology diagnosis and care, or prediction of medical and behavioral health conditions, AI is transforming healthcare in ways that could not have been envisioned a few decades ago.[18]

There are myriad legal considerations associated with these AI efforts. Aside from possible regulatory oversight of the technology and software itself, the delivery of AI-enabled care should be assessed for compliance with applicable privacy and security laws, possible application of research requirements, the evolving standard of care, and possible legal and ethical issues associated with AI bias.

This acceleration of AI is fostering collaborations among healthcare organizations and non-traditional technology and data partners. A prominent example of this is a broad 10-year collaboration between Partners HealthCare and GE Healthcare designed to accelerate AI and deep learning in every phase of the patient experience.[19] These joint ventures must be developed and overseen with care, with a clear agreement governing ownership and use of AI components and the data that results, and a shared understanding of how compliance will be implemented across the collaboration.

For healthcare delivery organizations that embark upon AI initiatives, it is imperative to have an integrated and multi-dimensional approach to AI oversight. This oversight must address in holistic fashion the complex clinical, technology, finance, strategy, legal, compliance, and ethical issues inherent in use of AI in healthcare. For the board, it will be important to understand at a structural level how technology innovation will be overseen, at both the management level and governance level. If the board believes it should have an ongoing role in the substantive issues associated with the future of AI in the organization, then the board must determine where within the governance structure this oversight will reside, and what board resources will be needed to make this oversight effective.

Private Equity and Venture Capital in Healthcare

PE and VC firms have been investing in healthcare for some time now. While this investment has been across the spectrum, there certainly has been vigorous investment activity in healthcare delivery, both in technology-enabled sectors and in targeted traditional provider areas such as home health, behavioral health, primary care, and larger physician organizations.[20] This investment has entered the acute inpatient sector as well, with mixed results.[21]

As health systems look for sources of capital and partners for expansion and innovation initiatives, prospective PE and VC partners may be considered. Health system boards evaluating these opportunities should pay close attention to key compliance considerations associated with these partnerships.

From a mission perspective, the board should make an unflinching assessment of the prospective investor's short-term and long-term goals. What is the estimated timeframe between now and the "liquidity event"? Is the PE/VC party willing to make firm commitments associated with capital investment and future operations? What will governance look like in the future, and how will that mission be protected?[22]

The introduction of PE into a community also can raise deep-seated concerns from elected officials and other leaders. This can create reputational issues and may impede needed regulatory or other government approvals for the transaction. Enforcement agencies also have been giving PE more scrutiny in health fraud enforcement matters.[23] If the PE party has been the subject of adverse regulatory or enforcement attention, this may enhance those concerns.

Conclusion

A health system governing board, in exercising its compliance oversight responsibilities, should periodically assess whether the structure and content of the compliance program is timely and effective. As disruptive forces continue to trigger fundamental changes in healthcare delivery, and as these changes are amplified by the COVID-19 era, it is timely for the board to consider practical measures to ensure the continuing effectiveness of the compliance program. Implementation of these measures should strike the appropriate balance in an era of competing priorities. Areas of particular focus may include service line expansion in emerging areas such as telehealth or home health; resumption of elective clinical care, surgeries, and procedures in the COVID-19 era; downsizing or discontinuation of services and facilities; deployment of AI or other forms of clinical innovation; and possible collaboration with PE or VC firms.

The Governance Institute thanks Anne Murphy, Partner, Arent Fox, LLP for contributing this article. She can be reached at anne.murphy@arentfox.com.

18 Thomas Davenport and Ravi Kalakota, "The Potential for Artificial Intelligence in Healthcare," *Future Healthcare Journal*, Royal College of Physicians, June 2019.
19 Jessica Bartlett, "Partners, GE Say They've Developed a Better Artificial Intelligence," *Boston Business Journal*, November 26, 2019; "Partners HealthCare and GE Healthcare Launch 10-Year Collaboration to Integrate Artificial Intelligence into Every Aspect of the Patient Journey" (press release), May 17, 2017.
20 Eileen Appelbaum and Rosemary Batt, "Private Equity Buyouts in Healthcare: Who Wins, Who Loses?," Institute for New Economic Thinking, March 15, 2020.
21 Harris Meyer, "Success of Private Equity Investment in Hospitals, Post-Acute to Be Determined," *Modern Healthcare*, August 21, 2019.
22 Heather Perlberg, "How Private Equity Is Ruining American Health Care," *Bloomberg Businessweek*, May 20, 2020.
23 Department of Justice, "Compounding Pharmacy, Two of Its Executives, and Private Equity Firm Agree to Pay $21.36 Million to Resolve False Claims Act Allegations" (press release), September 18, 2019.

Healthcare Boards Are Responsible for the "G" in ESG

By Liz Sweeney, Nutshell Associates LLC

The acronym ESG (environmental, social, and governance) was virtually unknown several years ago. Now, ESG is front and center in the lexicon of credit raters, investors, and employers. ESG is a dominant theme at investor conferences. Wall Street banks, mutual funds, and wealth management companies hire ESG analysts and researchers. Rating agencies publish frequently about the importance of ESG factors in credit ratings, with some even publishing formal ESG-themed scores. ESG factors are now cited by S&P Global Ratings as causing about a third of all rating changes for U.S. public finance debt issuers.[1] And within the ESG bucket, governance contributes most frequently to rating changes. According to S&P, in 2017 and 2018, "Governance was the most dominant factor affecting credit quality," accounting for a whopping 67 percent of ESG-related rating actions. Furthermore, most ESG-related rating actions are negative. According to Moody's, ESG considerations often have disproportionate downside credit risk, although the impact is not always negative.[2]

This increased ESG scrutiny, and especially the outsized impact of the "G" raises the imperative for healthcare organizations to understand ESG's expanding role in credit ratings and access to capital, track the metrics that credit raters and investors are following, and align presentation materials and disclosure accordingly. Perhaps more powerfully, boards can use the ESG framework to approach their role holistically, embracing the organization's interaction with stakeholders of all kinds and their impact locally, nationally, and even globally.

Boards can use the ESG framework to approach their role holistically, embracing the organization's interaction with stakeholders of all kinds and their impact locally, nationally, and even globally.

Close Siblings: ESG, Socially Responsible Investing, Impact Investing, Sustainable Investing

According to Moody's, the term ESG "refers to a broad range of qualitative and quantitative considerations that relate to the sustainability of an organization and to the broader impact on society of its businesses, investments, and activities. Examples include a company's carbon footprint, or the accountability of a company's management or a nation's government."[3]

Investors increasingly believe that applying ESG factors to enhance financial analysis of an organization helps identify potential risks and opportunities that traditional approaches don't. ESG is closely related to "social" investing strategies, including socially responsible investing, where investment opportunities are actively excluded or included based on ethical considerations; impact investing, where investments are selected to assist an organization to do something the investor considers positive for society; and sustainable investing, which seeks investment in organizations that combat climate change or environmental destruction and promote corporate responsibility. The various concepts are all aligned with the belief that organizations that behave responsibly to a broad range of stakeholders are also often brands that attract strong customer and employee loyalty, contributing to long-term stability and favorable investor returns.

How Does ESG Influence Credit Ratings?

Each rating agency takes a slightly different approach to evaluating ESG factors in their ratings. For the most part, ESG isn't a separate rating factor that has its own weight or score in the rating

Key Board Takeaways

Interest in ESG analysis is explosive among capital markets participants, including rating agencies and institutional investors. According to S&P Global, ESG factors contribute to about a third of credit rating actions on U.S. public finance debt. For these and other reasons, boards should:

- Recognize that ESG represents an admission by credit raters and investors that traditional credit metrics are not sufficient to capture certain factors that influence an organization's long-term success.
- Ensure their organizations are tracking ESG metrics and aligning presentation materials and disclosures to facilitate ESG analysis.
- Use the ESG framework to view the organization's social and environmental stewardship in a new, more holistic way.

1 "When U.S. Public Finance Ratings Change, ESG Factors Are Often the Reason," S&P Global Ratings, March 28, 2019.
2 "General Principles for Assessing Environmental, Social, and Governance Risks," Moody's Rating Methodology, January 2019.
3 Moody's Rating Methodology, January 2019.

methodology. In fact, if you read S&P, Moody's, and Fitch's non-profit healthcare rating methodologies, you won't find the phrase "environmental, social, and governance" anywhere. This can be rather confusing at first blush. How can ESG be such a sizable rating driver yet have no weight or even mentions in the methodology? The answer is partly about packaging—the rating agencies consider ESG factors to be present throughout the methodology already. Bundling a number of factors under the ESG umbrella doesn't require a change in methodologies. For example, the strength of an organization's strategy and execution is routinely assessed as part of rating analysis. That's not new. What is new is that today, if a rating agency downgrades a hospital due to a failure of strategy and execution, it will likely classify it as an ESG-related downgrade, under "governance."

Fitch Ratings general ESG risk elements for not-for-profit hospitals and health systems:

- Environmental elements:
  - » Emissions from operations
  - » Energy use in operations
  - » Water use in operations
  - » Management of medical waste
  - » Business disruption from climate change/environmental impacts changing human health requirements
- Social elements:
  - » Low-income patient access
  - » Data privacy/care quality and patient outcomes/controlled substance management/pricing transparency
  - » Labor negotiations and employee satisfaction/recruitment and retention of skilled healthcare workers
  - » Worker safety and accident prevention
  - » Social pressure to contain healthcare spending growth/sensitive political environment with impactful legislative changes
- Governance elements:
  - » Strategy development and implementation
  - » Board independence and effectiveness/ownership concentration
  - » Complexity, transparency, and related party transactions
  - » Quality and timing of financial disclosure

Today, if a rating agency downgrades a hospital due to a failure of strategy and execution, it will likely classify it as an ESG-related downgrade, under "governance."

ESG Analysis Is Not Just Repackaging

Bundling existing credit factors under the ESG banner theoretically doesn't affect ratings. For example, Fitch Ratings assigns "ESG Relevance Scores" to non-profit hospitals and health systems by assessing five environmental, five social, and four governance factors relevant to the healthcare sector, which are bundled into the ESG Relevance Score.[4] The ESG Relevance Score for a hospital doesn't affect its rating because any impactful elements within the 14 ESG factors are already assessed as part of the application of Fitch's rating methodology.

However, ESG analysis isn't just repackaging. There will likely be real and lasting impact of the increased focus on ESG. For investors, ESG analysis, including rating agency ESG scores, can be used as a screen for socially responsible investing of various kinds. Healthcare organizations that score well on these measures may gain access to a new and rapidly growing group of non-traditional investors whose philosophies are aligned more closely with the organization's mission and values than traditional investors. Additionally, while ESG factors are assessed within existing rating methodologies, the rating agencies' increased focus on ESG is a recognition that traditional measures of credit strength don't go far enough to assess an organization's long-term sustainability. In this way, ESG represents new scrutiny of factors that weren't traditionally part of the analysis. A look at Fitch's list of 14 ESG factors for non-profit healthcare organizations reveals some familiar credit factors, as well as others that haven't traditionally gotten much attention in rating analyses, particularly in the environmental and social categories (see sidebar).

Why Governance Is an Outsized Factor

All the rating agencies describe governance as the most common cause of ESG-related rating actions. This is largely because they take an expansive view of governance, encompassing most factors that are in the control of the organization. According to Moody's, "Unlike environmental and social risks, which may be driven by external factors such as regulation or demographic change, governance risks are largely issuer-driven. The impact of weak governance may affect scoring for [factors] influenced by an issuer's actions, planning, and policy decisions, such as a financial policy factor or leverage and coverage metrics."[5] Translation: when they score factors that weigh heavily in ratings such as financial metrics, they don't just assign scores based on number crunching; they also incorporate their view of financial governance into scores, which could mean a worse score than the numbers would otherwise indicate, which in turn can negatively impact the rating. In this manner, "governance" assumes a pervasive role in the application of the rating methodology, even for factors that were not traditionally considered governance-related.

Fitch Ratings also describes governance as the main driver of ESG-related credit impact: "This outcome is not surprising given that such issues as political stability, creditor rights, financial transparency, governance structure, government independence, and control of corruption are important rating considerations."[6]

4 "Introducing ESG Relevance Scores for Public Finance/Infrastructure," Fitch Ratings, May 16, 2019.
5 Moody's Rating Methodology, January 2019.
6 Fitch Ratings, May 16, 2019.

All the rating agencies describe governance as the most common cause of ESG-related rating actions.

In a review of recent rating actions, S&P categorized the following reasons as governance-related:[7]

- Failure to prevent money laundering
- Deficiencies in management, governance, and risk management
- Pension pressures
- Covenant breaches
- Oversight of merger and acquisitions
- Failure to post audited financial information

Taken together, it is clear that the "G" in ESG stands for a lot of things.

How Healthcare Boards Can Leverage ESG Concepts

The explosive growth of interest in ESG analysis signals that credit raters and investors believe traditional credit metrics are inadequate to measure long-term creditworthiness in an interconnected world where long-term success is increasingly tied to an organization's behaviors towards its environment, employees, vendors, customers, the local community, and even its role in global phenomenon such as climate change. At a minimum, healthcare organizations should start to collect data and monitor performance on ESG measures, then align disclosure and rating presentations with the ESG frameworks that the rating agencies are using. This will enable constructive two-way conversations about ESG factors, impress the rating analysts, and potentially open the door to new types of investors.

Rather than representing a new reporting burden on healthcare organizations, however, growth in ESG analysis is great news. Non-profit boards have always thought broadly about their role in the local community and the many stakeholders they serve, espousing values of social and environmental stewardship that their corporate brethren have only more recently begun to embrace. Many non-profits have felt frustrated in the past that credit raters and investors are, in their view, excessively focused on financial metrics over long-term sustainability.

For boards, ESG is an opportunity to organize the stakeholder engagement activities they have always espoused with the way capital markets now articulate those activities. Seeing the board's role through the ESG lens represents an opportunity to align the board's thinking about the organization's mission, vision, and strategy in new ways. For example, many boards have traditionally conducted siloed discussions of labor relations, access for underserved communities, data privacy, pricing transparency, and controlling growth in spending. Considering all of these holistically as part of the social mission—the "S" in ESG—may help boards to simplify the discussion and at the same time think about those things in new interconnected ways.

In many ways, capital markets are just catching up with the way non-profits have consistently managed their organizations. Does this mean that metrics like debt leverage and market share do not matter anymore? Of course not. But it does mean that credit raters and investors have opened the door to viewing those metrics with a different lens that incorporates other factors influencing long-term sustainability, and those factors generally are ones that non-profit boards have always embraced. Thinking about the board's role through the ESG lens can be a powerful way to guide the organization's activities and enhance investor relations at the same time.

The Governance Institute thanks Liz Sweeney, President of Nutshell Associates LLC, board member at the University of Maryland Medical System (UMMS), and former Managing Director at S&P Global Ratings, for contributing this article. She can be reached at liz@nutshellassociates.com.

7 S&P Global Ratings, March 28, 2019; "The Role of Environmental, Social, and Governance Rating Factors in Our Analysis," S&P Global Ratings, September 19, 2019.

Strategic Options in the Wake of COVID

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the most strategic options. Financially strong organizations will develop the capabilities needed for the new environment. They will have greater ability to tolerate the risks inherent in the post-COVID environment, and they will have greater influence in important payer and government policy decisions.

Larger, more financially strong organizations will take advantage of the opportunity to grow. At the same time, organizations with less financial wherewithal will align with market leaders or, in some cases, restructure or close. Organizations with superb telehealth capabilities, including non-traditional regional and national competitors, will have a far stronger position than previously.

Organizational role. In defining a role for this future landscape, organizational leaders must begin by setting aside allegiance to previous strategies. A new world requires fresh eyes and what Amazon's Jeff Bezos calls a "beginner's mind."

With that context, leaders will need information: What degree of damage have we suffered? What is our forecast for the next 90–120 days? The next year? What is the status of our clinical and non-clinical workforce? What options do we have for changing our cost structure? What is the financial and strategic position of others in our market? Our region? Organizations will need to develop a clear point of view about the future environment, and the characteristics and capabilities needed for success. They will need to undertake an honest—possibly humbling—assessment of their capabilities for that environment.

Hospital and health system boards and senior leaders should view their core missions in light of the likely future environment: Does this new world present new opportunities to influence social determinants of health? To dramatically improve the efficiency of healthcare delivery? To create a more accessible and engaging experience of healthcare? To prepare for the next black swan event?

> Today, while data and analysis continue to be vital—in fact, they need to be more sophisticated than ever—the COVID upheaval has elevated the task of assessing strategic options.

Then comes the hardest work of all: identifying strategic options to make a meaningful difference in the new environment. For example:

- How can the organization best serve its community by honing its capabilities for the safest, most efficient, most convenient care within its local market?
- Should it focus on enhancing its employed clinicians?
- Should it complement its capabilities with those of another hospital or system through some form of partnership?
- Should it reach out to non-traditional partners—such as retail pharmacy chains or big tech players—to round out its consumer-facing services and non-hospital footprint?
- Should it take a regional view—furthering its strength, capabilities, and relevance by joining a regional leader or by forming a new system?
- How should payer and employer relations change?

Imagination and Invention

In the past, assessing strategic options had a certain analytical bent. Market share, financials, competitor data, and a list of established strategic paths came together to yield a handful of options for the future. Today, while data and analysis continue to be vital—in fact, they need to be more sophisticated than ever—the COVID upheaval has elevated the task of assessing strategic options.

Imagination is the ability to bring forth a new idea—to look into the future and see its elements in a new combination and with a new outcome. *Invention* is the hard and smart work of building what the mind imagines into a new reality, mastering existing tools and materials, building new ones, and creating new structures and processes to yield new outcomes.

In the COVID crisis, assessing strategic options requires imagination and invention. Hospitals have been hit hard. They have been hit so hard that there is no going back to their previous state of being. However, with the loss of the existing world comes the possibility of creating a better one. It is a time for hospital leaders to imagine a better future and get down to work inventing it.

The Governance Institute thanks Ryan Gish, Managing Director, Jeff Kilpatrick, Managing Director, and Mark Grube, Managing Director and National Strategy Leader, Kaufman, Hall & Associates, LLC, for contributing this article. *They can be reached at rgish@kaufmanhall.com, jkilpatrick@kaufmanhall.com, and mgrube@kaufmanhall.com.*

Medicine's Emerging Third Eye

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Another example of new medical "third eye" capabilities is computational pathology. Computational pathology is actually quite similar to radiomics, in that images are the primary data source.[6] However, rather than X-rays, it uses digitized histopathologic tissue sections. Once again, by dint of having "seen" numerous examples of a particular disease or condition, these platforms can suggest diagnoses to clinicians by "seeing" patterns that human beings may not discern.[7] In addition to assisting with making difficult or nuanced diagnostic recommendations, this technology may be increasingly valuable as a first-line tool for triaging pathology decision making, as the clinical pathology physician workforce is both rapidly aging and shrinking in the United States, while demand for pathologic interpretation continues to increase.[8]

Other advances are being deployed using different medical data sources. Clinical proteomics has the ability to measure thousands of the human body's proteins at one time, and discern patterns of expression of these proteins that can not only provide for real-time human biology insights (such as percent visceral or body fat, VO2 max, and other measurements—from a blood sample alone!), but also predict events (such as the future risk of heart attack, stroke, or diabetic complications).[9] The body has 20,000 canonical ("basic") protein structures, and until recently only hundreds could be measured simultaneously. However, by the use of a novel measurement approach, the number has grown quickly to more than 7,000, and this is enough to get a "full body signal" and correlate an individual's expression pattern to other patterns "seen" by "the machine" in the past. Proteins are particularly important as, unlike genes, their expression is dynamic and changes over time, and can therefore reflect age, illness, environmental exposures, and other impacts on human biology (and consequently disease) that genes cannot. Some first-in-class protein expression pattern tests have recently been released, and a lot more are on the horizon.[10] As this is measuring a "pattern" of biologic activity never before available, it may well be able to identify individual risks conventional diagnostic approaches cannot.

Board Considerations

While there will be resistance to their use by some clinicians, board members should be interested in the thoughtful application of these technologies for a number of reasons. First, the use of cutting-edge tools such as these could have competitive advantages in markets where differentiation is important. However, more important is the potential to begin to render healthcare delivery more efficient, effective, and equitable. As we move from a system that focuses not only on acute care, but one that is increasingly invested in promoting and maintaining health, as well as eliminating healthcare access inequity (the need for both laid bare by the COVID-19 pandemic), new "intelligent" technologies will have to be deployed, as there will never be enough trained manpower to do all the work needed in a new model of care. These tools have the ability to make clinicians much more efficient and "extend" their reach. In the case of those such as clinical proteomics, they can also lower the cost of care and therefore make it more accessible—as "big box" diagnostics are needed less frequently or are only used when necessary.

Board members should ask their chief medical and information officers if these types of technologies are being used, or investigated, and how leaders are "socializing" their use when there is fear among some that these will replace physician competencies, and therefore, some physicians and their jobs as well. The fact is that they will not—they will make physician practice more productive and impactful, and eventually give them more time for the human interactions often lacking in modern medicine.

Whether you ascribe or not to the mystical and religious belief in a "third eye" capability, it is indeed very real in the context of medical diagnostics. These approaches will increasingly be capable of seeing the unseen, understanding the unknowable, and even predicting the future. The impact promises to be substantial.

The Governance Institute thanks Roy Smythe, M.D., Chief Executive Officer, SomaLogic, Inc., for contributing this article. He can be reached at rsmythe@somalogic.com.

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Embracing and Accelerating Healthcare Change Amidst COVID-19

By Brian Silverstein, M.D., The Chartis Group

In the past few months, COVID-19 has turned the world upside down, particularly in healthcare. While there is still much uncertainty around the virus, the long-term imperative to transform the health system remains critical.

We have known the issues that plague our healthcare delivery system and for the last decade, if not longer, we have struggled to make significant progress. We have tried to become more patient-friendly, embrace value-based care delivery, and focus on population health. These key strategies were important before COVID-19 and continue to be the keys to success in the future. What could be different is whether we can seize this moment to accelerate meaningful change.

Key Healthcare Strategies

It has been recognized for some time that healthcare is not particularly **patient-friendly.** Whether it was asking patients to come to the doctor just to get test results or packed doctors schedules, there have long been efficiency and experience challenges. In the past few months, we have seen great benefits and efficiency gains for both patients and providers alike in a greater use of virtual care. However, the delivery business model had not yet allowed the necessary changes to innovate the patient journey and incorporate a greater use of virtual care.

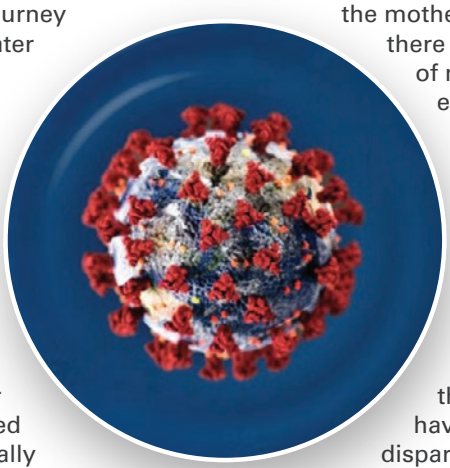
Value-based care delivery has been a concept discussed for decades but its implementation has proven to be illusive. Healthcare delivery today is supported by a variable pricing model where a small number of commercially insured patients pay substantially more for primary elective services to support a delivery model to serve all payer types. Efforts to move away from this model have been very slow and difficult to implement.

The concept of **population health** not only makes sense on paper; it also does in practice. Looking at a group of people and segmenting them to determine what services can benefit their health and then proactively reaching out to ensure they are cared for is an excellent clinical and business model. The need for "sick" care diminishes and the benefits are proven. However, this business model has not been able to be replicated or scaled throughout the country.

COVID Is Accelerating Change

Despite the best intentions and strong evidence supporting the migration to consumer-centric, value-based care delivery and a focus on population health, there have been countless barriers to achieving the requisite systematic change necessary to reimagine the entire healthcare industry. Very few foresaw a pandemic being a booster rocket to the pace of change—and yet, in the past several months, we have seen numerous signs of rapid innovation.

We all are living with COVID-19 every day, and the delivery system has been forced to adapt. Rapidly, providers have had to reevaluate their entire business and delivery models. This crisis has forced a rate of change that was unimaginable. Necessity is the mother of innovation and there has been a surplus of need. Providers have embraced remote care and payment is now in place. Systems are reevaluating every aspect of operations in a way to reduce costs. New care delivery models are being implemented that are focused on the patient. While we have long seen health disparities persist, the pandemic has been a bright spotlight on the myriad ways in which social determinants of health shape outcomes and experience.



Uncertainty can be paralyzing; yet in the age of COVID, many organizations have quickly driven to action. As organizations move from the initial surge preparation and response to managing in the age of COVID-19, the fundamentals still apply. Healthcare is very much a local service with dynamics that will continue to vary from one market to another. The payer dynamic may get even more complicated as they issue premium rebates for this year; yet they may raise rates for next year. Employers are already challenged to keep their businesses afloat and healthcare costs are going to take on a new urgency. Your market may be different and there may be more changes yet to come.

While no one knows with certainty what is going to happen in the future, it appears that COVID-19 has changed healthcare in a way that was unimaginable just months before. The opportunity to contain COVID-19 has long passed; it will be a factor that we will need to manage for months, if not years, ahead. As we think about the changes we are making today, they are not temporary measures but rather an acceleration of strategies we have been pursuing for years. This industry must say goodbye to incremental change. Hopefully this will be the enduring silver lining from this crisis.

Key Board Takeaways

- Key strategies before COVID-19—such as increasing consumer-centric care, value-based care delivery, and population health efforts—remain relevant in the era of COVID-19. Ensure your organization is still pursuing these critical strategies and has not lost sight of them in the chaos of the pandemic.
- COVID-19 is a propellant that is accelerating change. Consider this an opportunity and look at new ways to improve the quality and access of care and reduce costs.
- Rapid change can create a lot of distractions—keep focused on long-term strategic priorities.
- Imagine a future that does not exist today. It is critical for leadership to have an innovative mindset as they consider forward-looking strategies for success.
- Remember that local market dynamics still rule the day.

The Governance Institute thanks Brian Silverstein, M.D., Consulting Director, The Chartis Group, and Governance Institute Advisor, for contributing this article. He can be reached at bsilverstein@chartis.com.