

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

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**H**ealthcare 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.

**I**t 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.<sup>1</sup>

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,

## 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.

and a disciplined means for revisiting and adapting to this uncertainty on an ongoing basis.

**A**s 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

<sup>1</sup> *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.<sup>2</sup>

**I**f 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.<sup>3</sup> Similarly, the OIG publicizes federal and state criminal and civil enforcement actions.<sup>4</sup> 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](http://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:<sup>5</sup>

- 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.<sup>6</sup> 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.<sup>7</sup>
- Federal Medicaid waivers in the context of COVID-19, and state and local emergency orders and suspension of healthcare regulations.<sup>8</sup>
- Application of shifting federal and state regulation, and commercial payer policies, regarding telehealth service delivery, covered services, coding, and reimbursement.<sup>9</sup>

**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.<sup>10</sup> 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](http://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.<sup>11</sup>

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.<sup>12</sup> 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.<sup>13</sup> 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.<sup>14</sup> 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.<sup>15</sup>



### Downsizing of Services or Closure of Facilities

As was discussed at length in a recent article for The Governance Institute,<sup>16</sup> 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.<sup>17</sup> 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](http://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.<sup>18</sup>

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.<sup>19</sup> 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.<sup>20</sup> This investment has entered the acute inpatient sector as well, with mixed results.<sup>21</sup>

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?<sup>22</sup>

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.<sup>23</sup> 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](mailto: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.