

Academic Health Focus

Best Practices in Academic Medical Center Compliance Oversight

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Introduction

It goes without saying that every healthcare delivery organization must have an effective compliance program, and that the governing board must exercise appropriate oversight of it. As discussed in a recent article for The Governance Institute,¹ the board must assure that the compliance program adapts to changes in government enforcement priorities and enterprise innovations.

For academic medical center (AMC) boards in particular, this requires attention to compliance across the organization's complex corporate structure; the AMC's likely emphasis on innovation in areas such as artificial intelligence (AI) and its resulting relationships with unaffiliated parties; and traditional AMC hot button compliance areas such as resident and student supervision, research activities, and conflicts of interest (COI).

Key Oversight Considerations

Consistency in enterprise-wide compliance. AMCs inevitably have complex organizational structures,

¹ Anne M. Murphy, "[Welcome to the Future: A Healthcare Board's Practical Guide to New Compliance Program Priorities.](#)" BoardRoom Press, The Governance Institute, August 2020.

Key Board Takeaways

Below are items for AMC boards to consider as they refine their compliance programs:

- Assure that the organization's compliance program is integrated and consistently applied across all organizations in the enterprise.
- Evaluate the compliance culture of a prospective corporate affiliate pre-transaction and once affiliated, create a plan to integrate it into the enterprise compliance program.
- Be mindful of innovation activities involving collaboration with industry and AI because they can raise numerous legal, compliance, ethical, and reputational considerations.
- Prioritize compliance oversight to assure that both the board and the enterprise are well-positioned to address mission-critical issues.
- Assure that the organization remains vigilant in other AMC compliance focus areas such as resident and student management and supervision, research compliance, and COI management.

and no two look exactly alike. There is wide variation in the relationship between the AMC itself and the related medical school, the affiliated clinician organizations, the affiliated community hospitals, and myriad other organizations that are considered part of the AMC enterprise. The AMC board should have a clear understanding as to how the compliance programs for these organizations are assured to be consistent and coordinated and should periodically revisit with management the effectiveness of this integration. There is no single "right" way to do this—but it is imperative that the written compliance plans and protocols, as

well as operations, be integrated.

This integration mandate also should emphasize how the AMC evaluates an organization for its compliance culture pre-corporate affiliation with the AMC enterprise and once affiliated, how its compliance program is fully brought under the enterprise umbrella. Recent guidance² from the U.S. Department of Justice now makes clear that an effective compliance program should assure orderly compliance-related due diligence

² U.S. Department of Justice, Criminal Division, [Evaluation of Corporate Compliance Programs](#) (updated June 2020).

before a corporate affiliation is completed, along with a thoughtful plan for post-affiliation compliance integration.

Adjustment of the AMC compliance program to fully meet innovation initiatives.

The healthcare news is filled with reports of AMCs partnering with industry titans such as Google, Microsoft, Apple, and Amazon in various forms of innovation that entail access to clinical data, and may involve joint development of new clinical tools, combined research, and AI. The AMC board must assure that it has effective oversight of these cutting-edge activities—from a compliance perspective and otherwise.

Board competencies. A threshold question for the AMC board is whether it has the appropriate capabilities and resources to achieve effective compliance oversight of these innovation arrangements. This requires an assessment of whether the current board composition includes those with AI and related complex data experience and, if yes, whether these board members are actively involved in the compliance oversight function of the board. It may also be appropriate to consider whether the board wants independent external advice on these topics. Finally, the board as a whole should receive education and information regarding these innovation initiatives, and a subset of the board likely should be charged with a deeper understanding and closer oversight.

Non-traditional AMC relationships with industry to advance innovation.

The rapid expansion of innovation-oriented relationships between AMCs and industry has been spurred by technological advances, the commitment by industry leaders to the healthcare space, and the universal recognition that the clinical data and research experience that serves as fuel to innovation resides in healthcare providers such as AMCs. For AMCs, this activity is motivated largely by a mission to advance healthcare quality and research, but also comes with the ever-clearer recognition that these data are an important AMC asset with significant commercial value.

On a broad level, the board should evaluate with management how the organization has adjusted its structure to assure the inter-disciplinary management of innovation arrangements. This might entail a statement of principles related to innovation and AI, as well as a dedicated working group or office responsible for innovation. Recognizing that there is limited definitive legal, compliance, ethical, and risk management guidance at this time—especially as it relates to AI arrangements—it is important that this inter-disciplinary team include senior representatives from those parts of the organization. Fundamental questions regarding the potential for bias in application of algorithms, and the extent of transparency with patients, should be treated as essential mission and strategic matters.

AMC boards have a responsibility to understand these innovation arrangements, and to assure they are consistent with compliance principles, as well as the organization’s ethical, reputational, and transparency imperatives. The recent DOJ guidelines discussed above indicate that an effective compliance program should assess third party contractual partners and contract terms from a compliance perspective, and that would seem particularly important for innovation arrangement partners.

Moreover, the board should have a mechanism for being presented with key terms of innovation contracts to assure that these core enterprise priorities are met. Mission-critical contract elements include the type of data being accessed (e.g. minimum necessary or de-identified), the purpose and mechanism for data use, rights and responsibilities as to the data being input and the resulting intellectual property, compliance responsibilities between the parties, and limitation of liability and related insurance requirements.

A recent federal lawsuit against Google, The University of Chicago Medical Center, and the University of Chicago underscores the potential legal and compliance risks associated with these innovation arrangements, along with ancillary public scrutiny. Although the lawsuit was dismissed³ in September for lack of demonstrated damages by the plaintiff, it alleged violation of patients’ rights related to the sharing by the AMC of patient data to Google, including under HIPAA and other laws. The stated purpose of the arrangement was to apply AI techniques to de-identified electronic health records, in order to predict hospitalizations and better identify

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³ [Matt Dinerstein v. Google, LLC, No. 19 C 4311](#) (United States District Court Northern District of Illinois Eastern Division, September 4, 2020).

patients with declining health. The plaintiff, as part of a purported class, claimed the shared information contained date stamps and free text notes, thus rendering the data identifiable.

While this plaintiff did not prevail, it is reasonable to expect future litigation in this area, as well as close assessment of these arrangements in the public domain. The well-publicized legislative scrutiny⁴ of the Google “Project Nightingale” relationship with Ascension is one such example.

Sustained attention to traditional AMC compliance hot button areas.

While it is important for AMC boards

4 [Elizabeth Warrern, Richard Blumenthal, Bill Cassidy, M.D. to Joseph R. Impiccicche](#), March 2, 2020, United States Senate.

to focus on emerging compliance areas, it should not come at the expense of sustained vigilance regarding resident and student compliance considerations, research compliance, and active management of COI issues. Assuming the AMC has well-developed procedures, staffing, and reporting relationships for these established compliance priorities, the board should receive periodic reports on these topics, and assure that the organization is availing itself of the robust external compliance best practices resources available through membership organizations and otherwise.

Conclusion

AMC boards should assure that the organization’s compliance program is integrated and consistently applied across all organizations in the enterprise. The compliance

culture of a prospective corporate affiliate should be evaluated by the AMC pre-transaction and once affiliated, there should be a concerted plan to integrate it into the enterprise compliance program. Innovation activities of an AMC, particularly those involving collaboration with industry and AI, raise numerous novel legal, compliance, ethical, and reputational considerations. AMC boards should prioritize its compliance oversight to assure that both the board and the enterprise are well-positioned to address these mission-critical issues. Finally, the board should assure that in these rapidly changing times, the AMC remains vigilant in other AMC compliance focus areas such as resident and student management and supervision, research compliance, and COI management.

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