



BNA's Health Law Reporter™

Reproduced with permission from BNA's Health Law Reporter, 26 HLR 1595, 11/2/17. Copyright © 2017 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

Emerging Fiduciary Oversight Issues for Academic Medical Center Leadership and Its Legal Counsel



By Anne Murphy

Anne Murphy is a partner with Hinckley Allen LLP in its Boston office. Anne focuses her practice on advising academic medical centers, health systems, and other provider organizations. She can be reached at (617) 378-4368 or amurphy@hinckleyallen.com.

Introduction

Academic Medical Center (AMC) leadership and its legal counsel face emerging fiduciary considerations that can be organized around the three elements of the AMC mission: clinical care delivery, research, and education. These considerations stem from pressing strategic and operational risks for AMCs that traditionally have not been viewed within the domain of risk management, and have not always been a primary focus of legal counsel's advice regarding fiduciary duties. While some of these factors are not unique to AMCs, a number of them disproportionately impact this health-care provider segment. Taken together, these considerations provide a portfolio of opportunity and risk that is largely distinct to AMCs.

AMCs are built on a tripartite mission foundation that requires the simultaneous advancement of clinical care, research and education. Traditionally, this multi-faceted mission has been seen as the great strength of academic medicine. Increasingly, however, cost containment and related forces within the United States health-care delivery system have pressured AMCs to adapt to a new reality. In almost all instances, AMCs must now refresh their value proposition to the marketplace, and frequently must counter the perception that they are high cost enterprises that have difficulty responding to rapid change. At the same time, academic medicine is standing on the precipice of explosive opportunity, driven by technological and scientific advances.

For AMC leaders, this new reality requires an understanding of the numerous strategic, operational, financial, human capital, technology and compliance matters impacting the organization's compounded mission. AMC fiduciaries—whether they are officers or directors—should deploy a systematic approach to marshalling this complexity into a decision-making structure that recognizes risk and opportunity, honors the tripartite mission, and allows for streamlined action. Put in traditional legal terms, AMC legal counsel need to assure that AMC leaders are exercising the duty of care by being both adequately informed and sufficiently engaged in oversight across an increasingly complex and diverse array of risk-related issues.

Clinical Care Delivery

AMC margins, historically dependent on fee for service reimbursement for highly specialized care, are under substantial pressure, and it is expected that this trend will accelerate.

Mission and Strategic Considerations

For AMC fiduciaries, this margin pressure requires a robust effort to develop and implement transformative clinical care strategies that allow for successful participation in payment models based on value-based purchasing and risk assumption. This strategy development must consider the following:

The Need for Scale and a Comprehensive Delivery Network

AMC leadership should be unflinching in recognizing the need to achieve sufficient scale. As detailed in the Association of American Medical Colleges (“AAMC”) 2014 report entitled “Advancing the Academic Health System for the Future” (“[AAMC Health Systems Report](#)”), this scale can be achieved on a regional, national or international basis. In many cases, an AMC may adopt a combination of strategies, for example by participating in a regional network for the full spectrum of care, while also building a narrow network or similar product that is offered nationally in a clinical area of strength.

A significant potential fiduciary vulnerability for AMC leadership is persisting in the belief that the AMC can lead development of a health care provider system which, standing alone, will achieve sufficient scale over the long haul. By [some accounts](#), such a system should target 1 to 1.5 million covered lives to thrive in a population health environment. For many AMC-led systems, it would be very difficult to achieve this scale organically, so AMC fiduciaries should have a shared understanding of their scale aspirations, and of the need to formulate a clear organizational strategy that acknowledges them.

As a result of the scale imperative, many AMCs will need to develop corporate or joint venture relationships with other large regional or national health care systems. In some cases, the AMC might be required to relinquish corporate control to become the academic brand for a much larger system. In other cases, the AMC system might combine or venture with another system in a manner that preserves a substantial measure of corporate autonomy for the AMC. Regardless of the form, an integrated delivery system clearly must include a clinical practitioner network with sufficient primary care capacity, as well as outpatient/ambulatory, subacute and post-acute care.

The Need for Operations Conducive to Value-Based Purchasing

It is important for AMC fiduciaries to assure that operations position the organization for value-based purchasing. This typically requires multiple simultaneous initiatives.

AMCs must be increasingly facile in accepting risk-based contracts across population pools, in many cases collaborating with non-traditional partners such as payers. Because most AMCs have a relatively high percentage of revenue derived from Medicare and Medicaid, identifying a viable strategy for operating in Medicare and Medicaid managed care programs should be a priority. In the context of commercial insurance, it may be fruitful to develop reimbursement strategies tied to chronic disease state management and the recognized higher complexity of AMC patient populations. And, with direct-to-employer contracting, narrow network offerings in areas of clinical strength (such as joint replacement or cardiac surgery) likely will be based on bundled payment models incorporating value based purchasing principles.

The value-based purchasing model is premised on reimbursement consequences tied to quality outcomes. This demands proactive quality assessment and management, along with sustained consideration of social determinants of health. For AMCs, there may be special opportunity to utilize technology and research developments to formulate patient engagement innovations, and to position research operations as a powerful tool in improving health-care quality and access.

Sustained quality oversight by AMC fiduciaries should recognize that meeting quality metrics tied to reimbursement will be a moving target. As all hospitals and health systems focus on specific quality metrics, aggregated performance will improve and each provider organization likely will need to redouble its efforts. In other words, it will become progressively more difficult to move quality and patient safety performance dials, as low hanging fruit is eliminated and the average performance of provider organizations improves. For AMCs, this will affect not only their ability to thrive in a value-based purchasing climate, but also will drive reputational factors such as U.S. News and World Report rankings.

The Need for Rapid Cycle Innovation

AMCs must contain and manage costs in anticipation of overall revenue flattening or reduction. At the same time, it will be important to make strategic investments in order to accelerate innovation, support emerging consumer-driven technologies (such as telehealth), and decentralize service delivery.

In 2016, the AAMC published a report entitled “Academic Medicine in 2025: Notable Trends and Five Future Forces” (“[AAMC 2025 Report](#)”), which delineates several key future trends in academic medicine. In relation to clinical care delivery, the report predicts sophisticated and rapid prototyping cycles for care and therapy improvements, in which academic medicine partners with technology and data organizations. The report also suggests that AMCs should explore the deployment of biosensors and other consumer tools, with a likely future surge of “flipped clinics” in which patient encounters are more in depth (and informed by biosensing data). Moreover, the report predicts that population health management will be enhanced by “high resolution” data, ranging from personalized genetic profiles to aggregated big data that is better able to see macro health trends.

Emerging Compliance Considerations

While it is critical to highlight the importance of addressing emerging strategic and operational issues for AMCs through the lense of fiduciary oversight, it will be important also to consider the new legal and compliance issues resulting from changes in an AMC's approach to clinical care delivery. A few examples of potential issues include:

- An AMC that adopts an international medicine strategy with global locations will need to consider Foreign Corrupt Practices Act, unsettled and fluctuating immigration law requirements and other regulatory considerations. Similarly, it is advisable to assure that international medicine operations are fully synchronized with the AMC's compliance and legal offices.
- Direct to employer contracting with bundled payment for selected services may raise corporate practice of medicine and insurance law questions, particularly if the employer operates in numerous states.
- Telehealth and other consumer-driven remote access technology initiatives should be evaluated under state professional licensure and scope of practice laws, telehealth-specific informed consent requirements, government reimbursement constraints, data security and privacy laws, and state insurance laws governing reimbursement.

Research Activity

An AMC's tripartite mission requires a strategic approach in which research activities complement clinical operations. Importantly, bench and clinical research operations can enhance an AMC's overall reputation, attract prominent talent, and generate public and private grants and life sciences joint venture opportunities.

Mission and Strategic Considerations

AMCs and their affiliated universities vary significantly in how they handle bench and clinical research operations. In some cases, large universities undertake technology development and transfer operations on behalf of the AMC; in other cases, the AMC itself plays a central role in this process. A number of AMCs have robust internal teams dedicated to sophisticated research relationships with life sciences companies, in which technology development and transfer is addressed in a comprehensive manner. For many AMCs, however, the internal infrastructure for handling research ventures, intellectual property development and commercialization may benefit from renewed attention to determine if these activities should be supported by additional resources.

Clinical research activities also serve as an increasingly important AMC differentiator in terms of patient choice, as patients seek access to clinical trials. The rapid evolution of precision medicine and personalized medicine tools likely will accelerate this trend.

For AMC leaders, it will be important to develop an updated approach to technology development and transfer and intellectual property management, which increasingly focuses on collaboration with industry partners in life sciences, biotechnology, artificial intelligence and data management sectors. This trend is driven in part by reductions in government grant funding, but also is part of a sea change in favor of “networked discovery.” As described in

the AAMC 2025 Report, research is undergoing a radical shift, in which researchers work in diverse networks that cross substantive and institutional lines. Greater openness and collaboration around data and discovery is predicted to accelerate innovation, but will create obvious pressures in terms of traditional data ownership and intellectual property principles.

Emerging Compliance Considerations

As research activities in AMCs evolve, attendant compliance issues that will need to be re-addressed include:

- As relationships continue to expand among AMCs, universities and industry, it will be important to anticipate evolving conflict of interest (COI) scenarios. This may require updated COI policies that are conducive to ethical and principled collaboration with industry, along with a COI infrastructure that addresses in adequate fashion both clinician COI and research-related COI.
- In “networked discovery” environments, patient privacy, data ownership and intellectual property ownership considerations become more complex, and may require new policies and compliance tools. This complexity has been accompanied by a significant uptick in IP litigation, in which academic institutions and pharmaceutical companies are becoming more aggressive in asserting IP ownership claims. For academic medicine, this is the product of declining government research funding, an increased reliance on research revenue in comparison to clinical revenue, and legal risks and opportunities related to the patentability of innovations related to personalized medicine. (See, [Weisman, Boston Globe Article](#), 8/22/15; [Carlson, Star Tribune Article](#), 8/10/17).
- As telehealth continues to expand, it will become a more mainstream tool for advancing clinical trials and clinical research. This will trigger research-specific legal considerations and compliance strategies related to state professional licensure and professional scope of practice regulations, informed consent for clinical research trial subjects related to the use of telehealth, and data privacy and security considerations. (See Mazur, et al., [BNA Health Law Reporter Article](#), 6/9/16).

Educational Activity

The AMC educational mission typically encompasses the education of medical and other clinical students, along with residency and faculty training programs. These programs are undergoing substantial transformation, as on-demand learning platforms proliferate, and as simulation technologies become more sophisticated.

Mission and Strategic Considerations

Many AMCs are organizationally separate from the university with which they are affiliated; over time, the university may have become reliant upon fund transfers from the AMC's operating margins. As these AMC margins become uncertain, AMC leadership may find university fiduciaries asking whether a continued tight affiliation with the AMC poses unacceptable risk to the university. ([AAMC Health Systems Report](#); Garg, et al., [Academic medical centers: Transformational imperatives to succeed in the new era healthcare](#)). This potential tension between AMC and university fiduciary duties may require focused governing board attention by both parties.

As on-demand learning and simulation technology experiences rapid growth, academic medicine will need to adapt operations so that educational content is available in a personalized, mobile, and networked manner. This is expected to decrease hierarchy and structure in medical school education, which may require nimble adoption of technology and educational programming. ([AAMC 2025 Report](#)).

Faculty relationships and student engagement will continue to evolve in academic medicine, in a manner that will demand sustained transformational attention from AMC and university leadership. These issues include: bringing clarity to tenure policy (which can be the subject of confusion and controversy); [optimizing the role of nursing faculty in academic medicine](#); adopting a more [centralized and transparent approach to departmental funding](#) that is aligned with clinical and research priorities; and harmonizing policy and legal considerations when enhancing faculty and student diversity. With tenure policy in particular, an overall decline in reliance on medical school tenure track positions has been coupled with a shift over time in the meaning of tenure, as medical schools have reduced or eliminated financial guarantees associated with tenured status. (See, AAMC, [The Redistribution of](#)

[Tenure Tracks for U.S. Medical School Faculty: Clinical MD Faculty](#), May 2015; AAMC, [The Redistribution of Tenure Tracks for U.S. Medical School Faculty: Basic Science PhD Faculty](#), June 2015).

Emerging Compliance Considerations

In many cases, there will be substantial benefit in taking concerted steps to assure coordination between the compliance programs of the AMC and its affiliated university. As a general proposition, AMCs have had mature compliance programs for decades, whereas some universities have implemented these programs more recently. For an array of higher education compliance resources, see the [Higher Education Compliance Alliance](#). University legal compliance considerations related to educational strategy and operations include:

- Student diversity policies must be evaluated under robust legal and accreditation guidance, to assure that both the policies, and the precise manner in which they are implemented, are compliant. (See, [A Policy and Legal Syllabus for Diversity Programs at Colleges and Universities](#), College Board, May 2015).
- Gender misconduct and other behavioral and safety issues need to be managed proactively, and in a time of evolving federal guidance. These issues extend into faculty behaviors that may be seen as demeaning, intimidating or hostile.
- As many universities clarify or update tenure policies, and as the overall opportunity for tenure track appointments diminishes nationally, the potential for litigation challenging these actions needs to be considered and managed proactively.
- A distinctive array of privacy and information security requirements impact academic medicine. On the university side, in addition to compliance with federal and state privacy and security laws governing patient health information, laws protecting student information, such as the Family Educational Rights and Privacy Act, also must be satisfied.

Conclusion

It is important for AMC executives and governing boards to develop a fiduciary oversight approach that is expansive in defining, managing, and prioritizing emerging risk. Legal counsel play a vital role in guiding this process.

AMC risk certainly includes financial, compliance and legal perils, and also recognizes the potential harm to the organization of reputational and mission deficits. But perhaps as fundamental as this, fulfillment of AMC fiduciary duties must involve navigating strategic and operational risk and opportunity, which inevitably demands not only a disciplined and realistic examination of competencies and future environmental challenges, but also requires evaluating the risks associated with not taking an action.

The natural inclination of legal counsel often is to view risk primarily through the lense of legal and regulatory compliance, as well as litigation and government enforcement exposure. While this certainly is an essential component of risk management, these traditional legal risks should be integrated into the AMC's broader risk profile.

AMC "risk" should encompass both that with only negative potential (downside-only risk), as well as that with a positive potential (upside-potential risk). This distinction is particularly useful when considering the strategic and entrepreneurial opportunities presented to AMCs across clinical care, research, and education mission dimensions.