If you have questions or would like additional information on the material covered, please contact the author:

Elizabeth B. Carder-Thompson
Partner, Washington, D.C.
+1 202 414 9213
ecarder@reedsmith.com

Top 10 (or so) Legal Issues for Teaching Hospitals and Academic Medical Centers in 2014

Top Ten lists abound this time of year. This one is a somewhat expanded version of my University HealthSystem Consortium (UHC) luncheon presentation on January 23, 2014. It updates last year's list for UHC and highlights the top 10 daunting issues and questions confronting teaching hospitals and academic medical centers (AMCs) in the coming year.

1) ACA Madness, or Regulatory Change Marches On

The Affordable Care Act (ACA) continues to produce an avalanche of new agency regulations, and ongoing controversy across the country. The woes of the Healthcare.gov website and health care exchange enrollment continue, deadlines keep shifting, and the Supreme Court will this year decide the constitutionality of the contraceptive mandate. Given enrollment and budgeting uncertainties, AMCs cannot determine how they will fare under the new system. As Larry Levitt of the Kaiser Family Foundation recently wrote in JAMA, it's halftime for the ACA launch, and the issues themselves have changed somewhat. Questions for the coming year include:

- Will citizens pay their premiums?
- How large will the March enrollment surge be?
- What will the mix of enrollees be?
- Are low-income consumers enrolling?
- How will people perceive their coverage once they start using it?

A more fundamental question might be, will the public ultimately think all the disruptions in the health insurance marketplace were worth it? As one commentator wrote, there are going to be ACA winners and losers, but the problem is that even if most are winners, they're typically not the ones writing to their members of congress.

2) Corollary Medicaid Madness

Medicaid expansion controversies will doubtless continue. Currently, 23 states plan Medicaid expansion this year, and another three will do so but via an alternative methodology. Some 24 have chosen not to expand. Questions remain on how well the expansion states will actually implement the new systems, and whether the non-expanding states (many “Red States”) will change their minds, i.e., to obtain the temporary enhanced payments or in response to pressure from medically-underserved individuals and providers. Issues for AMCs – and indeed, for our society at large – continue to be how to care for our most needy citizens, such as at-risk children, in a cost-effective and manageable way, in the face of Medicaid funding shortfalls.

3) The Perfect Storm for Fraud and Abuse Investigation/Enforcement

Even a cursory review of the civil False Claims Act cases over the last year demonstrates that potential whistleblowers – qui tam relators – are *everywhere*, in every health care delivery system operating today. Many have dollar signs dancing in their eyes, envisioning their “cut” of a million or even billion dollar false claim, kickback, or Stark settlement. The past year’s crop of relators -- shockingly -- included in-house general counsel, billing and compliance staff, auditors, and even patients, and multiple AMCs were caught in the frenzy. Since the pipeline of FCA cases moves very slowly, this trend doubtless will continue, with a line of new cases likely initiated once CMS begins to publish its “Sunshine” results this year (that is, reported payments by drug and device manufacturers to physicians and teaching hospitals). Moreover, massive amounts of federal and state dollars are targeted for enforcement, and the provisions of the underlying statutes themselves are expansive (e.g., the requirement to return all “overpayments” in 60 days or face FCA enforcement). Yet, the government continues to insist on strict construction of statutes like Stark – where a missing physician signature on a contract can totally trump the fact that a clinical need existed and medically necessary services were appropriately rendered. One hospital’s potential pending Stark settlement is estimated at $1.1 billion.

4) Uneasy Alliances Among Hospitals, Physicians, Non-Physician Practitioners

Pressures from government-mandated quality measures and the need for cost containment are driving alignment efforts among hospitals, physicians, and non-physician practitioners, but no one is entirely sure how well this is going to work. As I wrote last year, true health care reform can only happen if physicians are engaged in the care delivery transformation, but efforts to effect this change are increasingly causing friction under our current system. Fraud and abuse restrictions on gain-sharing, corporate practice of medicine limits, state medical licensing laws – all will be tested in the coming months, as hospitals and physicians explore new and uneasy alliances. Accountable care organizations, bundled payment programs, and other evolving models of health care delivery will continue to emerge, but strain existing legal limits. In the face of resident shortages and ongoing cost pressures, more hospitals and AMCs are relying on nurse practitioners, hospitalists, and other non-physician professionals, but a new emphasis on the latter group may also force increased requirements for training, credentialing and the like.

5) Keeping up with Other Medicare Changes/Cost Controls

Aside from ACA enrollment-specific uncertainties, Medicare changes and cost controls pose continuing challenges for AMCs and teaching hospitals. Hospitals are facing straight reimbursement cuts under ACA market basket update reductions and the so-called productivity adjustment, plus separate layers of sequestration cuts and billions in disproportionate share payment reductions. On top of that, the myriad of hospital quality initiatives – readmissions policies, value based purchasing, hospital-acquired conditions -- pose special difficulties for institutions caring for low income and chronically ill populations. It remains to be seen whether the carrot-and-stick approach to cost control has any real impact in the long run – something the Robert Wood Johnson Foundation has questioned in the past. With Medicare graduate medical education (GME) support minimal, the question inevitably arises how to maintain high training quality in teaching hospitals. Further, individual payment measures like the CMS "Two Midnights" policy may require facilities to make specific policy and operational changes, once CMS eventually begins implementation. Finally, 2014 may see long-term reform in the sustainable growth rate (SGR) payment system -- bipartisan bills have been approved by Senate Finance, the House Ways and Means, and the House Energy and Commerce Committees, and a unified plan recently was unveiled, but more than $100 billion in spending offsets still must be identified. The watchword has to be continued vigilance.

6) The Brave New World of Privacy and Security Regulation

The new HITECH regulations are posing a variety of facility and institution challenges, beyond the challenges posed by wider provider use of electronic health records, portable media and mobile health technologies, cloud computing, and social media generally. The "BYOD" or bring your own device environment tests the ability of employers and health care institutions alike to safeguard personal health information in an effective manner. Federal enforcement from the Office for Civil Rights as well as the FTC is at an all-time high, and states are getting into the act as well, with large monetary settlements stemming from myriad fact patterns, from lost laptops to failures to scrub digital copier hard drives to disposal of medical records in unlocked recycling tubs.

7) Implementing and Maintaining a Truly "Effective" Compliance Program

More attention than ever needs to be paid to compliance, given the new alignments and alliances among hospitals and physicians, the difficult environment of evolving regulations and cost-control measures, and the climate of draconian fraud and abuse enforcement activity. But how much is enough – and how much oversight do those measures require? The OIG's corporate integrity agreements continue to place increasing responsibility on boards of directors for compliance oversight – as well as certifications of compliance – raising inevitable questions regarding the qualification and commitment of current health provider governing bodies. The challenging compliance environment places new stresses on employee relations, and some companies and institutions have resorted to obtaining signed agreements from employees promising to disclose fraud and abuse issues, and not to initiate false claims actions – an employment practice that will be scrutinized in several cases in the coming year.

8) How To Continue and Honor the Research Imperative

The unique role AMCs have always filled in the research arena appears in unusual jeopardy this year, given that sequestration has slashed NIH research funding and demoralized the medical/scientific community to boot. The result? Many teaching hospital faculty members have simply stopped conducting research, there are fewer patients enrolled in NIH-funded trials, there are fewer graduate students, and ongoing research projects with significant implications for patients and for public health have been reduced and may be terminated altogether. Moreover, past research alliances with pharmaceutical and device companies are under unprecedented scrutiny, and it remains to be seen whether the pending "Sunshine Act" publication on financial arrangements among industry, physicians, and teaching hospitals will have a further chilling effect.

9) Thinning of the Provider Herds and Surviving Antitrust Scrutiny

As I noted at this time last year, not every hospital or AMC can expect to survive in the era of health reform, and 2014 is likely to see bankruptcies and closures above and beyond those that are an outgrowth of consolidation generally. The cost controls and other pressures leading providers to alignments and consolidations (some potentially including insurers) will necessarily result in tensions with antitrust compliance. As we continue moving toward integrated delivery systems and coordinated care, hospitals and AMCs will need to guard against perceived abuses of market power. An added risk factor is that private party litigation is increasing.

10) The Jury's Still Out…..

Rather than selecting one Number 10, I've included several possibilities….

Labor and Employment: The "Noel Canning" case will be decided this year, assessing the validity of the Administration's recess appointments to the NLRB – which in turn could throw into question the validity of many cases decided by those pro-union appointees. Union organizing efforts at hospitals and health systems will continue, and employers will have to deal with continued uses and abuses of social media like Facebook to air grievances and the like. Finally, wage/hour questions will continue on what employees are entitled to overtime pay.

Genomic Dilemmas: While discrimination on the basis of genetic information – e.g., by insurance companies and employers -- is prohibited by federal law, the medical community appears uncertain as to exactly how such complex and evolving information should be used in treating patients, and what liabilities may arise if the information causes mistakes in medical care. On the flip side, as genomic information becomes more common, will medical centers be liable for not using it, in the event genomics becomes a standard of care that potentially improves outcomes? Moreover, will AMCs lose market share if they fail to incorporate genomics in their services?

Tax: Previously tax-exempt institutions may face challenges to their status once their rolls of uninsured patients presumably decline under health reform and under more stringent IRS guidelines in this area. Allegedly excessive executive compensation has threatened some institutions, along with too-high levels of unrelated business income.

Futility Cases: Finally, participants in the January 23rd UHC luncheon agreed that 2014 is likely to see increasing instances of disputes involving alleged “futile” care. One well-publicized California case early this year involved a 13-year old left brain dead following a tonsillectomy, whose parents insisted on continuing life support. Another in Texas pitted a husband seeking to withdraw life support for his brain dead pregnant wife, against the treating hospital which cited a state law prohibiting it from withdrawing life-sustaining treatment from a pregnant patient. These difficult and controversial cases promise to escalate during the year.

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