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Outlook 2014

Health Plan Regulation, Medicaid Top List Of Issues for 2014 Amid ACA Uncertainty

With government, industry and consumers still coming to grips with all aspects of the Affordable Care Act, *BNA's Health Law Reporter*'s editorial advisory board voted **health plan regulation** the top health law issue of 2014.

The troubled rollout of health-care exchanges and massive uncertainty about implementation of the ACA stood out as prime themes that will add to the business and legal challenges for health plans in the new year, board members said.

Moreover, political battles over the ACA are far from over. ''The viability of the ACA will be an incredibly potent lightening rod for the 2014 mid-term elections,'' Thomas Wm. Mayo, SMU/Dedman School of Law, Dallas, Texas, said.

The expansion of **Medicaid** and the pivotal role the program plays in the ACA scheme edged it to second on the Top 10 list.

''Both the political debate over Medicaid expansion and the reality of increased Medicaid enrollment make Medicaid a Top 10 issue for 2014,'' Douglas A. Hastings, Epstein Becker Green PC, Washington, said. ''Health plans serving the Medicaid population will be under scrutiny, but will have significant opportunities for expansion.''

The linchpin role of **hospital/physician alignment** in cost containment and improvements in quality of care guarantees that the issue will be hot in 2014, board members said, ranking it third. ''The reality is that everything that is being contemplated by health reform and health system transformation is completely dependent upon physician and health system alignment,'' Howard T. Wall III, RegionalCare Hospital Partners Inc., Brentwood, Tenn., said.

Sky high rates of prosecutions under federal and state health-care fraud laws place **fraud and abuse** at or near the top of the legal risks facing health-care organizations, board members said, voting the topic fourth on the Top 10 list for 2014.

''Given that new decisions under the False Claims Act now emerge daily, fraud and abuse enforcement, litigation, and regulatory counseling will remain strong in 2014,'' Richard Raskin, Sidley Austin LLP, Chicago, said.

The sheer size of the **Medicare** program and its importance to providers make it a perennial top issue, and 2014 is no exception, board members said, ranking it number five.

Although ''it's not clear that Medicare will face significant new legal or regulatory issues,'' Kirk Nahra, Wiley Rein LLP, Washington, said, ''the entire environment surrounding Medicare will be challenged because of all the problems with the exchanges and related pressure that will be placed on the biggest government health-care programs.''

Pressing privacy and security challenges in the health-care industry, combined with ramped up enforcement and new compliance requirements, prompted board members to rank **health information technology** sixth on the list for 2014.

The pace of health industry consolidations is expected to continue in 2014, making **antitrust** the seventh most important health-care topic of the year. Board members predicted an increase in more creative deal structures. ''With the emphasis on consolidation and cooperation among physicians and institutional or system-wide health-care providers, the antitrust laws and related waivers have once again come front and

Health Law Reporter's Top 10 for 2014

1. Health insurance exchange rollout and ACA litigation make **health plan regulation** the top issue.
2. As state **Medicaid** program reforms under ACA continue, implementation questions grow.
3. The push for greater **hospital/physician alignment** intensifies.
4. **Fraud and abuse** remains a top compliance and FCA liability focal point.
5. Changing **Medicare** reimbursement schemes exacerbate provider financial woes.
6. **Health information and technology** poses implementation, compliance and liability challenges.
7. Consolidation and alignment pressures make **antitrust** a central compliance concern.
8. **Taxation** headaches abound as ACA initiatives directed at exempt hospitals, health insurers and employers mature.
9. Providers continue to struggle with **labor and employment** law pressures.
10. **Corporate governance** challenges provider organizations as director responsibilities and compliance risks increase.

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center,'' Katherine Benesch, Benesch & Associates LLC, Princeton, N.J., said.

Compliance and enforcement for exempt hospitals continue to pose significant challenges, making **taxation** the eighth most important health-care issue for 2014.

Gerald M. Griffith, Jones Day, Chicago, said the Internal Revenue Service will be busy in 2014 riding herd on providers and provider collaborations. ''With the explosion of ancillary joint ventures and cutting edge affiliation models involving both for-profits and nonprofits, the IRS exam teams are likely to see a lot of what they view as low hanging fruit,'' he said.

Labor and employment will continue to significantly impact the labor-intensive health-care industry, board members said. Providers should keep an eye out for labor union initiatives, wage/hour issues, scrutiny from the National Labor Relations Board and regulatory and enforcement actions from the Department of Labor—all reasons the issue placed ninth.

The 10th-ranked issue, **corporate governance**, will continue to be on the front burner for the health-care sector, board members said, saying practitioners will need to up their game in the new year.

1. Health Plan Regulation. Uncertainties surrounding the implementation of the ACA and the health insurance exchanges, including their problem-plagued rollout, dominated board members' comments and propelled health plan regulation into the number one slot on the Top 10 list. Board members also cited legal challenges, including one to the IRS rule that defines which individuals are entitled to receive tax credits for buying insurance on an exchange, as top health plan regulation developments to watch in the coming year.

Health plan regulation is ''the heart and soul'' of the ACA, Tom Mayo said.

''The states, the Supreme Court and the Affordable Care Act are all contributing to major regulatory and substantive changes at all levels in the health-care industry,'' Katherine Benesch said, referring to 2014 as ''the year of health plan regulation.''

Vickie Yates Brown, Frost Brown Todd LLC, Louisville, Ky., cited ''the tremendous upheaval that has been and will continue to be caused by the huge changes in health plan regulation.'' She noted that the ''insurance industry and businesses have not had as much time as many other facets of the health-care industry to get accustomed to the impending changes.''

Mark A. Kadzielski, Pepper Hamilton LLP, Los Angeles, predicted that the ''convoluted world of federal and state regulations will become more complex this year, as HHS and state regulators ramp up ACA-related operational and enforcement efforts.''

Shaky Exchange Rollout. Board members foresee health plan regulation issues arising from the ''shaky'' start of the federal and state health insurance exchanges.

''With the uneven and troubled rollout of the access and coverage provisions of the Affordable Care Act in the fourth quarter of 2013, health plan regulation will be a hot-button issue in 2014,'' Doug Hastings said. He questioned ''what the enrollment figures will look like by'' the March deadline for buying health insurance, as well as whether the exchanges will ''work reasonably well as shopping sites.''

Douglas Ross, Davis Wright Tremaine LLP, Seattle, said one of the ''critical issues in 2014 is whether the federal exchange can be fixed in time to head off a catastrophic failure of health reform.'' He asked whether ''delays in enrollment [will] result in an adverse selection death spiral.''

T.J. Sullivan, Drinker Biddle & Reath LLP, Washington, said ''all eyes are on the plans and exchanges now, not just to see whether HealthCare.gov will work, but also judging coverage, medical loss ratio and premium rate issues, as well as planning to avoid the upcoming Cadillac tax.''

John D. Blum, Loyola University Chicago Institute for Health Law, Chicago, also focused on health-care exchange implementation, saying the real test will be how the exchanges ''cope with risk over time and whether their respective pools will be balanced enough to make this portion of the ACA viable without longer term subsidies and sharp premium increases.''

''The shaky rollout, the deep partisan divide and the continued lack of public support open the door to the possibility of some delay or repeal of important elements'' of the ACA, Howard Wall said.

It will be interesting to see ''whether the requisite numbers will sign up to make the new plans work,'' Benesch said. ''If not, grave questions will be raised about the financing of the new system, and this could have a profound effect on hospitals, doctors, and other providers and patients.''

Post-Operational Issues. Resolving the operational issues surrounding the exchanges, however, won't end the debate over this key component of health reform, board members said.

Hastings suggested that there may be further amendments to the exchange rules that will make ''pricing and compliance for plans more difficult.'' He questioned whether there will be ''audits and/or allegations of noncompliance under the MLR (medical loss ratio) regulations.'' Additionally, he asked, ''will risk adjustment rules change based on who enrolls?''

Mayo said that once the websites for the exchanges are operating smoothly, ''the so-called 'back door issues' loom large.'' For example, he said, one question is whether all of the actuarial assumptions upon which the ACA is based will come true.

Much of the success of the exchanges, Ross said, depends on narrow networks. Providers and patients already ''are pushing for broader networks, and politicians and insurance commissioners are responding by threatening to force networks to open to all providers.'' However, he said, ''health reform can't drive costs down if all willing providers are able to force their way into health plans.''

''The exchange program has been an enormous challenge for health plans, even before the operational difficulties arose,'' Kirk Nahra said. ''Now, in addition to the added time and cost associated with all of the exchange problems, we see an increased likelihood that the benefits of the exchanges for the plans will likely be smaller and the challenges and costs greater.''

Lowell C. Brown, Arent Fox, Los Angeles, said health plan regulation ''will continue to be a mess.'' He added that ''political pressure will increase as plans become very handy 'bad guys,' an appellation some of them will deserve.''

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Overarching Issue for 2014: ACA Implementation

The thread running through most Top 10 issues for 2014 is, of course, ACA implementation. According to Howard A. Burde, Howard Burde Health Law LLC, Wayne, Pa., implementation of the law is the ''only topic for the coming year,'' albeit one with numerous subtopics, including health plan regulation. Several other board members singled out the ACA and its implementation as the biggest issue for 2014.

In particular, Burde said to look for issues surrounding health insurance exchanges, including the number of people who enroll and the demographics of enrollees (''young, old, sick, healthy?''), whether employees will lose employer-based coverage and whether certain ''mandates will be delayed or simply ignored by the administration.''

He also said to keep an eye on how the courts interpret certain ACA provisions. Look for judicial rulings in litigation over federal exchange subsidies and the contraceptive mandate, he said, including how the Supreme Court will rule on the contraceptive mandate's application to for-profit, secular corporations. Politically, the ACA will have an impact on the mid-term elections, he said.

Mark Waxman said that even in areas the ACA does not impact, ''its impetus to reshape the system is driving new thinking.'' He questioned whether the law will ''stand up to the next round of legal challenges, whether the challenging rollout problems will continue, and whether there will be other 'hidden' issues in the ACA that surface.''

The health-care exchanges, Kirk Nahra said, ''have been so worrisome that they have become synonymous with 'Obamacare,' and have distracted from everything else that is going with health-care reform. The ongoing political battles have set out a reform program that would be difficult to make work in any event, and the administration's failure in making the exchange piece work have made the overall concerns even better. Once again, it seems like we have missed a chance to try out meaningful reform.''

Harkening back to some key drivers behind adoption of the ACA, such as insuring the uninsured and improving health-care quality, Doug Hastings said that ''responding to the health-care needs and costs of the overlapping populations of those who are clinically at-risk or socially disadvantaged remains a fundamental moral and financial challenge in the United States.''

Those populations include the frail elderly, he said, as well as ''the homeless; dual eligibles; low income individuals, especially within racial and ethnic minorities and rural Americans; at-risk young children; the mentally ill or cognitively impaired; and those with multiple or complex chronic conditions.''

''For example, many beneficiaries who are dually eligible for Medicare and Medicaid are both economically disadvantaged (86 percent have incomes below 150 percent of the federal poverty level) and in poor health (60 percent have multiple chronic conditions),'' he said.

Despite these challenges, ''coordinated care efforts with this highly vulnerable group has the biggest opportunity to improve quality of lives, lower costs, and reduce disparities.'' he said.

Information Security, Risk Management. W. Reece Hirsch, Morgan, Lewis & Bockius LLP, San Francisco, said that while the security of the federal ACA website has been in the spotlight, ''the more significant risks to data probably exist in the state insurance exchanges.''

Fredric J. Entin's thoughts on health plan regulation turned to risk management. ''Providers cannot assume the responsibility for treating defined populations without the ability to take on and manage the attendant financial risk,'' he said. Entin is with Polsinelli Shughart PC, Chicago.

While some health-care systems already sponsor their own health plans, and thus have experience coordinating care and risk, others may be forced to create or buy health plans, he said. ''Look for affiliations between providers and plans ranging from outright acquisitions to exclusive arrangements to tight contractual relationships.'' Entin said the ''drivers of these necessary affiliations could be either the plan or the provider. It will interesting to see who has greater success.''

2. Medicaid. Medicaid's expansion under the ACA virtually ensured that it would be a hot issue in 2014, according to board members, who placed it second on the Top 10 list. Several states have opted not to loosen eligibility requirements, but they could be forced to rethink their positions as the Medicaid population increases and budget shortfalls leave them without adequate funds to cover medical care for the poor, board members said.

''Medicaid presents federalism issues as well as the full array of plan regulation, provider regulation, antitrust, fraud and abuse and other legal issues,'' Doug Hastings said. ''Changing payment and delivery models applicable to Medicaid present both business opportunities and care improvement opportunities, and lots of legal issues'' for consideration in the coming year, he said.

The biggest issue, many advisory board members said, involves the ACA's Medicaid expansion provision—''the one part of the ACA that is going forward at a breakneck speed,'' according to Lowell Brown.

Vickie Brown said states that ''decided to expand Medicaid will have to determine how to absorb the extra costs when their existing Medicaid budgets are already running a significant deficit.'' Another issue that hasn't been adequately addressed by these states, she said, is ''how or if they will continue to provide long-term care benefits.''

Those same states ''will be pressed to ensure adequate provider participation,'' John Blum said. And ''those that refused expansion will still need to respond to service pressures from the medically underserved.''

Higher enrollments will spark more state Medicaid fraud and abuse activities, and ''Medicaid waiver pro-

grams for special needs populations will be particularly problematic as home and community waivers limit access to institutional care,'' Blum said.

J. Mark Waxman, Foley & Lardner, Boston, asked whether the ''volume of new patients'' created by Medicaid expansion and other ACA programs will ''make up for the continued challenge to the economic position of providers. And if not, what will happen?''

'Political Football.' Tom Mayo noted that states that opted out of the expansion program may still adopt it ''and get federal funds for doing so.'' There already has been ''some later-year movement in red states that have decided the offer in the ACA is too good to pass up,'' he said.

Howard Wall agreed, saying the ''political football being played by GOP governors over whether to accept Medicaid expansion will continue in 2014.'' He asked whether opt-out states will move ''beyond politics and find ways to obtain waivers to create innovative Medicaid models that will cover more residents and put the programs on a more sustainable footing long term'' or ''continue to resist expansion and leave millions without access to health care.''

''Early successes and strong pressure from provider groups could push more states in the direction of accepting expansion, especially if it can be packaged as a politically acceptable Medicaid 'reform' program,'' Wall said.

In the opinion of Jack A. Rovner, The Health Law Consultancy, Chicago, ''financial and political pressure to 'accept' federally financed Medicaid expansion is likely to be sufficient for continued adoption of Medicaid expansion by more and more states in 2014.''

Even in opt-out states, Medicaid ''enrollment is exploding,'' Doug Ross said. ''The future of Medicaid is very much tied up in the success or failure of the public exchanges,'' he added. Future issues to watch, he said, include the ''impact of expanded Medicaid spending on the federal fisc'' and its impact on ''states as they (inevitably) have to take over this funding.''

3. Hospital/Physician Alignment. Board members ranked the increased pressure for greater alignment of hospitals and physicians as a Top 10 issue, putting the issue on the list for only the second time. Citing its relationship to cost containment strategies and quality of care improvements, board members continue to see the development of new hospital/physician alignment approaches as a key component of their response to health-care reform under the ACA.

Katherine Benesch ranked physician/hospital alignment high on her Top 10 list, citing dramatic changes that are expected to continue. ''Collaboration and cooperation are the touchstones that have replaced the antagonistic relationship that existed in the past between hospitals and their medical staffs,'' she said.

According to Dawn Crumel, Meritus Health, Hagerstown, Md., better alignment between her hospital and the physicians who treat patients there is the primary focus of her efforts to help her hospital reduce costs.

''Hospitals and physicians will have to align more to have common goals of changing how patients access health care and the quality of that care,'' she said. ''We have started an accountable care organization through our physician hospital organization and are exploring a management services organization as part of a regional alliance with two other community hospitals.''

''Trying to run a health-care system without a strong, closely aligned physician component isn't like trying to herd cats, it's worse,'' Gerry Griffith said. ''Now more than ever, physicians are feeling the fiscal pain of actual or threatened cuts in payment and uncertainties over what the health-care delivery system of the future will look like.''

As a result, he said, ''there will continue to be a strong wave of practice acquisitions, employment, comanagement arrangements, and joint ventures as phy-

Quality of Care: A Driving Force in 2014

The push for improved quality of care, whether as a function of patient entitlement, professional provider duty or compliance and reimbursement reality led most board members to cite it as a major force in the 2014 health law landscape.

Medicare rules tying reimbursements to quality of care, new tools to measure quality, the reliability of those tools and how and when they can be implemented all received board members' attention.

For example, Lowell Brown said ''cost pressure will force people to ask hard questions about what they are getting for their money, and whether providers really can do more for less.''

Fred Entin cited reimbursement models that turn on quality. The ''health-care industry has now had several years of tinkering with payment models that are based on outcomes rather than volume. Whether the models already in place have actually improved care and outcomes is still being debated.''

The debate, Entin said, ''is fueled by disagreements over how to measure quality and to whom and how to attribute contribution to quality. Because there is no clear answer at this time,'' there will be ''more attempts at using more robust information to identify when and how outcomes have been raised. Over time, those techniques and measures that gain credibility will move from optional to preferred to mandatory.''

John Blum agreed that ''quality innovations will continue,'' but said ''the area remains one laden with major challenges.''

One quality measurement tool that is receiving a great deal of attention is ''big data,'' a reference to massive data sets that now can be aggregated from multiple sources and analyzed to spot trends. Jack Rovner asked whether this tool can ''deliver meaningful measures of care quality that may allow for meaningful transparency in provider performance.''

Mark Kadzielski predicted the emphasis on quality will result in ''more reductions in government payments for poor quality events.'' In addition, in states like California, fines will be assessed against health-care providers for poor quality, he said. ''The culture of safety is being replaced by a culture of blame.''

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sicians try to preserve the practices they've worked so hard to build over the years.''

T.J. Sullivan said that much of his workload is driven by issues related to consolidation and alignment undertaken by hospitals to protect market share and by physicians to bring about practice simplification and income protection.

Mark Waxman said hospital/physician alignment is the inevitable result of the pressures brought to bear under the ACA but that, because so little is known about how ACA implementation will ultimately evolve, ''we are running a large unplanned experiment, without a control group.'' Although health-care financing reforms are forcing changes in structures, no one seems to know how much consolidation is too much, he said.

''Trying to run a health-care system without a strong, closely aligned physician component isn't like trying to herd cats, it's worse.''

—Gerald M. Griffith, Jones Day, Chicago

Mark Kadzielski agreed, noting that the rapid formation of ACOs ''has physicians scurrying to lock in an 'affiliation,' without any true basis for evaluating what they are getting into.'' Because of this, ''the potential for disaster and disappointment in such arrangements is high.''

Response to Upheaval. Board members said the changes are the unavoidable response to financial and practice challenges associated with an evolving health-care industry. Jack Rovner cited the ''continued upheaval in health-care delivery, including ACOs as the current 'flavor of the month' to 'fix' health care, as a force that will continue to drive hospital system acquisition and employment of physicians. He said this effort ''will test whether the result will be 'integrated/coordinated' care delivery that takes 'risk'—like the 'old' staff-model HMO—or provider market power that drives price inflation and stifles innovation.''

Toby G. Singer, Jones Day, Washington, agreed, cautioning that hospital/physician integration will receive significant attention by antitrust law enforcers and private plaintiffs, including suits by providers shut out of deals, as well as employers and plans challenging higher premiums.

''Physician behavior is crucial to electronic medical record (EMR) adoption under the HITECH Act and elimination of clinical waste by eliminating 'defensive medicine' practices,'' Howard Wall said. ''Lowering cost and improving quality by utilizing checklists and following evidence-based best practices, improving the patient experience and outcomes by adopting a multidisciplinary team based, patient centered approach to care, and transforming traditional medical staff models to reflect the new ways of delivering care, are critical components to the ACA's success that rely on better alignment.''

''The struggle is how to create economic models—traditional employment, co-management, gain sharing, to name a few—that create the economic incentives to encourage behaviors that will improve safety and lower costs without running afoul of the anti-kickback statute, Stark and other laws,'' Wall added.

According to Fred Entin, ''those providers that accept the proposition that taking responsibility for defined populations is the future, will continue to acquire, affiliate or align with the assets necessary to meet the expectations of the government and private payers who are headed in that direction.'' They will obviously need physicians committed to the same goal, he added.

Lowell Brown said that ''everyone will realize they are all in the same boat and as more and more money is dumped into a single bucket, physicians and hospitals will be forced to find ways to live together profitably.'' He predicted that, with alignment pressure, ''the corporate practice of medicine bar, still alive in five large states, will finally begin to fade into oblivion.''

Brown also said that, as hospitals consolidate, ACOs form and physicians team up with institutional providers, ''the old medical staff model will continue to feel mounting pressure.''

Physician Perspective. Michael F. Schaff, Wilentz, Goldman & Spitzer PA, Woodbridge, N.J., said the alignment phenomenon is moving very rapidly because both physicians and hospitals are scared about how to best respond to reimbursement and practice changes precipitated by the ACA. ''The problem is, however, that no one is quite sure whether they have the right model to move forward because they don't know what the ultimate impact of the ACA will be,'' Schaff said.

''The process of negotiating new alignment relationships in 2014—whether through employment contracts, physician enterprise arrangements, or leasing of physician practices—while building in flexibility to unwind the arrangement down the road will give rise to a lot of risk,'' Schaff said. ''For physicians, it will be important to maintain an even playing field, one that is fair now and that permits the physician to realign at the end of the period covered by an agreement without unreasonable restrictions.''

''Physicians also need to recognize at the inception of any transaction—when they have the greatest leverage—that the deal may need to be unwound and prepare for that event as though it were a certainty,'' Schaff continued. ''Physicians should be vigilant, for example, in making sure any restrictive covenants in an arrangement disappear upon termination so they can resume their practice unencumbered.''

4. Fraud and Abuse. Nearly all board members identified fraud and abuse as a practice and compliance area that will consume the attention of both providers and practitioners in 2014, and a number ranked it as their top issue. Whether driven by the government's desire to save money or the bounty paid to successful qui tam relators, the complexity of fraud and abuse compliance in the midst of ACA rollout will make 2014 another challenging year, they predicted.

Fraud and abuse ''is always at the top, and always will be, because this is the government's best bet to save money and prevent widespread gaming of the health-care system,'' T.J. Sullivan said.

Lowell Brown agreed. ''The feds think 'there is gold in them thar hills,' and they're probably right. The enforcement agencies won't let up on a bit, and innocent providers who are already trying to cope with Medicare and Medicaid provider pricing pressures will get caught in the net.''

Kirk Nahra said fraud and abuse continues to be a top provider concern ''because the ongoing difficulties of health-care reform will place enormous financial pressures on the federal government to recover funds and because the administration will face substantial challenges in finding the difficult balance between getting these programs up and running and at the same time enforcing the rules.''

Nahra cited some ''useful history from the Medicare Part D program'' where the government allowed program participants to work out the kinks before pursuing fraud activities. ''Whether they will approach these issues the same way will be an enormously important question,'' he said.

''The challenge at the regulatory stage is to build regulations that let these programs work and allow/encourage companies to participate, but an overly aggressive anti-fraud program is in tension with that,'' he said. ''In addition, the rules are so complicated and remain unfinished in many situations that there are few good answers about how to actually handle some of the key issues.''

Robert L. Roth, Hooper, Lundy & Bookman, Washington, said that ''big settlement and case awards will always be big news'' and predicted that ''enforcement statistics will continue to grow until more clarity comes to the payment/anti-referral/fraud and abuse rules, which has, so far, proven to be elusive.''

False Claims. Fraud and abuse is a ''a week in-week out topic that will continue to impact providers,'' Mark Waxman said.

Recent case law, ''led by the *United States v. Halifax Hosp. Med. Ctr.* decision [2013 BL 314276, M.D. Fla., No. 6:09-cv-1002, 11/13/13], places in question a number of alignment efforts, and emphasizes how careful providers must be in structuring their arrangements,'' he said, adding ''with more potential qui tam plaintiffs out there every day, one cannot be too careful.''

Howard Wall predicted 2014 ''will be a very active year for fraud and abuse as the pace of hospital/physician alignment continues and the scrutiny from Recovery Audit Contractors, qui tam relators and government enforcers continues to increase.''

Citing *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.* (D.S.C., No. 3:05-cv-2858), Wall also said transactions will come under continued scrutiny as getting legal advice and a valuation in the future ''will only be useful if they are received from individuals and firms with specialized expertise.''

Richard Raskin said fraud and abuse ''has to be at the top of any health-care organization's list of legal risks,'' he said.

Because of ''the inherent complexity of health-care billing, coding, and reimbursement; the variety of tools at the government's disposal for the investigation of, and enforcement against, possible violations; and the strong incentives for whistle-blowers to bring qui tam actions on the government's behalf, virtually every health-care entity—and even many non-health-care entities that do business with health-care entities—face significant fraud and abuse risk,'' he said.

Doug Ross noted that the FCA is continuing to evolve and that fraud and abuse issues are likely to arise as by-products of the ACA and the changing nature of health-care reimbursement. He cited the question of who is responsible for misstatements by consumers regarding eligibility for subsidies submitted by and paid directly to the carriers. He also pointed to the pending U.S. Supreme Court case, *United States ex rel. Nathan v. Takeda Pharm. N. Am.* (U.S., No. 12-1349) that will address the split in the circuits on the specificity required for FCA claims under Fed. R. Civ. P. 9(b).

Sanford V. Teplitzky, Ober Kaler, Baltimore, Md., noted that recent FCA settlements ''have drawn into question certain arrangements and factors that have long gone under the radar'' and that ''simply structuring an arrangement as an employment relationship no longer ends the analysis.'' Other investigations and settlements have involved situations in which the party had obtained a fair market valuation. ''Again, the message here is that the existence of the valuation is not as important as the manner in which the valuation was conducted,'' he said.

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—RICHARD RASKIN, SIDLEY AUSTIN, CHICAGO

Teplitzky also pointed to a number of recent cases, including *Halifax*, that raise the question of whether Stark currently applies to Medicaid. ''Although CMS has generally taken the position that it does not, DOJ, and the courts, may be moving in a different direction,'' he said. ''This 'trend' raises a number of significant concerns with respect to the issue of how much is the potential Stark overpayment and whether the FCA can now be used by relators to pursue awards based on Medicaid revenues resulting from referrals in the context of Stark noncompliant relationships.''

Self Disclosure. Teplitzky also noted that, although CMS's program for voluntary disclosures of Stark law violations continues to evolve and produce data, the data show that providers are utilizing the program but that cases are being resolved at a ''plodding'' pace. ''Providers are using the program, either because they believe that it is a worthwhile and meaningful opportunity to resolve a Stark overpayment, or because in light of the provisions of Fraud Enforcement Recovery Act and the ACA, they have no real choice,'' he said.

Although Teplitzky said CMS appears to be acting diligently and in good faith, the slow pace of case resolution is creating a backlog that is having serious, collateral ramifications. ''In the merger/acquisition context, noncompliant relationships are often not identified until during due diligence, so a lengthy disclosure/resolution process is creating significant problems with respect to efforts to move forward with the transaction closings, especially where there is insufficient guidance for the parties to determine how much to set aside to address the overpayment,'' he said.

Exchange Subsidies. Several board members mentioned fraud and abuse issues related to the nascent health insurance exchanges. Jack Rovner pointed to the ''somewhat surprising 'clarification' by the Department of Health and Human Services that federal premium and cost-sharing reduction subsidies for health insurance purchased on public exchanges are not 'federal health-care programs' subject to the federal fraud and

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abuse laws.'' That action ''leaves open how the federal government intends to police those subsidies for fraud and abuse, particularly with respect to providers and insureds,'' he said.

Teplitzky also noted the dispute over whether the new health-care exchanges under the ACA are subject to the federal anti-kickback statute. ''The HHS Secretary wrote that they are not. This letter was followed, within four days, by a response from CMS to the effect that 'maybe they are not, but you better be careful,' '' he observed.

''This issue is critical to those providers who are currently considering whether they can provide financial assistance to patients who would otherwise be unable to afford insurance under one of the exchanges,'' he said. ''This would certainly be a prudent move, in order to avoid the virtual certainty of nonpayment, but may raise regulatory and compliance concerns under the AKS and the federal prohibition against providing beneficiary inducements.''

5. Medicare. Medicare has always placed high on the Top 10 list, and changes wrought by the ACA may make it even more important this year, according to board members who ranked it fifth for 2014. Tensions will rise throughout 2014, they said, as the government sees lowering reimbursements as a way to manage its budget, despite an aging population that is increasingly dependent on Medicare. Additionally, statutory and regulatory payment reform initiatives may lead payers to reduce or reshape their networks.

Medicare is ''the 800-pound gorilla in terms of its impact on providers, institutional and individual,'' Tom Mayo observed. He expects ''greater scrutiny of reimbursement and even coverage issues going forward, considering Medicaid reform and the increased federal attention to (and role in regulating) private insurance.''

Mark Waxman said that Medicare ''remains the most important and dynamic portion of the health-care delivery dollar,'' although health reform ''impacts it in so many ways.''

Payer/Provider Tensions. Robert Roth said he sees ''provider/payer relationships getting more strained in 2014 and the coming years.'' He observed that ''there is an obvious and natural tension between providers and payers with regard to payment—providers want to receive more and payers want to pay less.''

''With regard to Medicare, and to a lesser extent Medicaid, the opportunities for providers to increase net payments from the fee-for-service programs have diminished over the years,'' Roth said.

Providers have tried to maximize reimbursements by ''(1) improving billing accuracy, (2) operationalizing the overpayment identification and refund process, and (3) selectively pursuing appeal and reopening opportunities,'' he said. Nevertheless, ''significant increases in net Medicare/Medicaid payments are difficult to achieve and the trend, in fact, is the opposite.''

Roth added that ''many providers have also responded by being more attentive to the contractual obligations of commercial payers and Medicare/Medicaid managed care plans. And, as the stakes get higher, both sides are trying to use market power to their advantage in contract negotiations.''

For example, he said, ''payers are seeking to exclude from their networks providers that they think are uncooperative, and providers with some market leverage are rejecting payment offers from plans that are viewed as unreasonable. In addition, it appears that providers, particularly those who are most sophisticated, are increasingly willing to use contractual dispute resolution remedies to seek payments they feel they deserve.''

Board members foresee still more significant changes to the Medicare system, brought about by the ACA and subsequent regulations. ACA incentive payment programs, like bundled payment, value-based purchasing and pay for performance, ''will be critical harbingers of future Medicare reimbursement policies,'' John Blum said.

Medicare is ''the 800-pound gorilla in terms of its impact on providers, institutional and individual.''

—Thomas Wm. Mayo, SMU/Dedman School of Law, Dallas

Howard Wall said that ''deeper cuts in provider reimbursement could be adopted as a 'pay for' to address other budget concerns.'' He said to look for freezes on physician pay, the expansion of the Medicare Advantage program, and the elimination of certain add-on programs as the government continues to look for ways to cut expenses.

''As reimbursements decline, the scramble for funding will only increase; so will efforts to economize and cut costs,'' Lowell Brown said.

Still, pressure to preserve and improve Medicare is rising, as ''the Baby Boomers are coming to Medicare in droves,'' Jack Rovner said.

6. Health Information and Technology. Emerging technologies, security and new regulations under the Health Insurance Portability and Accountability Act (HIPAA) will grab the attention of health law attorneys in 2014, board members predicted, leading them to rank health information and technology sixth on the Top 10 list. The issue also bleeds into other areas, they said. For example, ''big data'' projects may help answer some question about the quality of care, as information is accessed and analyzed to determine if health-care providers are meeting quality goals.

Several expected developments in the field of health information and technology ''are important to the future of the health-care industry,'' Kirk Nahra said. The ''impact of cloud computing on the industry is substantial, and there will be real pressure to both expand use of the cloud and increase oversight and regulatory protections for cloud data,'' he said.

Reece Hirsch said that, given ''the large volumes of medical information now stored in cloud servers, it seems inevitable that further regulatory scrutiny from the [Health and Human Services Department's Office for Civil Rights] can't be far away.'' He said that the ''HIPAA Final Rule makes clear that cloud computing providers are business associates, even if their personnel do not access the protected health information maintained in the cloud.''

The new rule will force business associates to adapt to the new regulatory environment, Hirsch said. ''Even though BA audits and investigations probably won't be on OCR's front burner in 2014, expect to start seeing

some high-profile BA enforcement matters in the coming year,'' he predicted.

EHRs. Use of electronic health records (EHRs) also is expanding, according to Nahra, but ''there are real challenges to linking EHRs through'' health information exchanges. ''These exchanges, while not generating the attention of the insurance exchanges, do not work much better, and there is no meaningful business plan for most the exchanges.''

Jack Rovner cited ''finding a sustainable business model for health information exchanges'' as one of the challenges for 2014, along with ''gaining industry interoperability and achieving 'meaningful use.' ''

Board members said "big data" will attract attention in the coming year.

Doug Ross said that ''Meaningful Use Stage 2 will push health-care providers to adopt new technologies with new privacy and security challenges, such as patient portals that raise particular challenges in the areas of access to minors' records and patient identity verification.''

Security, Enforcement. ''Issues related to security—cyber, data security practices, breaches, etc.—are an ongoing and real challenge, and even have a link to the [health insurance] exchanges as well,'' Nahra said, noting that ''the security rules are not yet final for the exchanges and few people seem to have confidence in the security arrangements.''

Mark Kadzielski predicted that ''privacy breaches will occur in astounding numbers, many related to only partially regulated mobile devices. In the health-care workplace, 'BYODs' [bring your own devices] also create extremely high risk for mishandling confidential information.''

Doug Hastings added that ''assuring patient privacy under federal, state and common law becomes exponentially more complicated,'' as the country moves to a ''21st century data system'' where information must move seamlessly between industry players. Further, he said, ''government enforcement in this area is ramping up.''

Nahra agreed that there may be ''significant HIPAA enforcement in 2014.'' He opined that ''OCR will start to enforce the new rules, if only to a limited extent, in particularly egregious cases.''

'Big Data': Can It Deliver? ''Some of the larger vendors to the healthcare industry will be exploring the possibilities and risks associated with health-care 'big data' projects, applying sophisticated data analytics tools to large databases of medical information to develop cutting-edge products and services,'' Hirsch said. ''OCR needs to provide more clarity on this subject or innovation may be stifled.''

Hastings and Rovner said the ''big data'' movement is one that will attract attention in the coming year. '' 'Big data' is a sought after 'solution' under the Affordable Care Act,'' Hastings said, while Rovner added that ''the value of mining 'big data' may be a big story in 2014 if it can deliver on the promise to improve care quality and transparency.''

Rovner added that health-care providers in the coming year will switch their focus from HIPAA to ICD-10. The rule implementing the new code set used to report medical diagnoses and inpatient procedures goes into effect Oct. 1.

Dawn Crumel confirmed that her hospital's information technology team is focusing on preparing for ICD-10. It also is ''collaborating with physicians on technology in innovative ways'' in order to ''show meaningful use.'' She also said the IT team is working on ''ensuring our security measures are prepared for malware attacks, which hospitals will see more of in 2014.''

7. Antitrust. Antitrust issues will continue to demand the attention of providers and their counsel as ACA-driven provider consolidation and payer initiatives designed to streamline provider networks draw reactions from government enforcers and private parties, board members said. The government's hand may be stayed somewhat if consistent with ACA reforms, but private parties allegedly injured through exclusion or unlawful restraints can be expected to press their claims, they added.

Toby Singer said that the ACA ''continues to disrupt market forces, leads to more and more provider and insurer consolidation that, of course, raises significant antitrust issues.'' Coupled with ''continued aggressiveness by the Obama administration as well as increasing private antitrust litigation, this means that antitrust issues will continue to be at the forefront in 2014,'' she said.

Doug Ross said he expects the Federal Trade Commission to continue to push providers, ''attacking some very small mergers and pushing hospitals and physicians even farther into the camp of nonbelievers in the virtues of competition.'' Although Ross said the impetus for more ''guidance'' from the antitrust agencies will build, ''whether we get some, and whether it's of any use if we do, are separate questions.''

"At some point the two halves of the administration—those promoting the ACA and care model transformation and those who are fighting health-care consolidation—will need to get on the same page."

—Howard T. Wall III, RegionalCare Hospital Partners, Brentwood, Tenn.

Gerry Griffith said the antitrust enforcement agencies ''will be faced with key policy decisions as they try to balance protecting competition with preserving access to health care in local communities nationwide and furthering the public policy underlying the ACA.'' How they respond ''could directly affect how successful those policies will be in the long term,'' he said.

Important Policy Issues. A simmering debate over the proper role of consolidation as part of health-care reform will continue to play out in 2014, board members said. Howard Wall pointed to the uptick in FTC and De-

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partment of Justice activity in the health-care space and noted that it is happening at the same time consolidation within the industry is accelerating.

''Does market consolidation within health care, which on the provider side is extremely decentralized, reduce competition and increase costs as the FTC and some economists believe or is consolidation, standardization and dramatic cost reductions the only way to achieve the long-term goals of higher quality and lower cost like it has in other sectors of the economy?'' Wall asked.

''At some point the two halves of the administration—those promoting the ACA and care model transformation and those who are fighting health-care consolidation—will need to get on the same page,'' he said.

Doug Hastings agreed, citing the same policy and legal debate over both provider and payer consolidation and predicting that the debate ''will continue to rage on in 2014.'' Given the current U.S. health-care system dynamic, ''there is tremendous pressure to collaborate, which for the most part is good, and network (nonchange of control), as well as M&A (change of control) transactions are proliferating,'' he said.

''As these combinations continue with no end in sight, further guidance from the antitrust agencies on the implication and application of evidence-based measures of quality and cost on the formation and operation of both mergers and network collaborations is needed,'' Hastings said.

Expect More Litigation. Board members also predicted litigation, whether initiated by private parties or government enforcers, won't slow down. ''New creative collaboration models, both horizontal and vertical, raise complex antitrust issues that can give rise to both government and private enforcement actions,'' Singer said, citing the cases involving St. Luke's Regional Medical Center in Idaho, which involve both private and government parties.

''The private case is a vertical case that involves referrals—the acquisition of a large physician group by a competing hospital system that is allegedly depriving the plaintiff hospital of needed referrals from the physician group,'' she said. ''The FTC, on the other hand, is alleging that the combination of the newly acquired group with the physicians the hospital system already employs will allow it to raise prices—which is a horizontal case.''

Richard Raskin said that antitrust should be near the top of the Top 10 list, particularly for health-care entities involved in consolidation efforts, joint ventures, ACOs and other network arrangements. ''Health care will remain one of the government's top priorities for antitrust enforcement, with pharmaceutical settlements, as well as allegations of exclusionary practices of manufacturers and providers with a substantial market share, continuing to draw close scrutiny,'' he said.

''Although government enforcers tend not to be concerned by narrower managed care networks (since such narrowing can lead to lower costs), expect to see additional private litigation challenging exclusion from managed care networks,'' Raskin predicted.

Jack Rovner cited uncertainty and disruption of ACA implementation as spurring payer and provider horizontal and vertical acquisitions, consolidations and joint ventures that will lead to intensified public and private antitrust scrutiny. ''I would also expect private actions challenging as 'exclusionary' payer moves to adopt tiered and narrowed networks,'' he added.

8. Taxation. A perennial issue for the tax-exempt hospital sector, taxation also draws the attention of health-care employers and payers who must address the application of new health insurance rules and taxes under the ACA, board members said. Although additional guidance is anticipated, exempt hospitals will, of course, continue to be challenged to comply with new IRS information gathering, reporting and filing requirements under the ACA, they added.

''I think we can expect aggressive enforcement efforts by the IRS on unrelated business income in particular, as well as seeing the first evidence of fallout from IRS review of Section 501(r)—the new requirements for nonprofit hospitals added by the ACA,'' Gerry Griffith said. ''Hospitals that have been more than busy enough focusing on the myriad other challenges under the ACA may be in for a rude awakening when the not so friendly local IRS agent shows up on their doorstep.''

''I predict the IRS will finally answer the one question that really matters'' and isn't addressed by the 501(c)(4) rules: ''What does 'primarily' mean?''

—T.J. Sullivan, Drinker Biddle & Reath, Washington

T.J. Sullivan agreed. ''The IRS is very busy implementing the ACA and managing the fallout from its 501(c)(4) Tea Party political activity debacle and new people are staffing the IRS TE/GE function from the commissioner to the director of exempt organizations and below,'' he said.

''We can expect more rulemaking and certainty around ACA issues and, unfortunately, more lawsuits to get timely answers on tax-exempt status,'' Sullivan continued. ''Most importantly, I predict the IRS will finally answer the one question that really matters and, inexplicably, the only question the new proposed 501(c)(4) regs don't address: What does 'primarily' mean in the context of how much political activity a social welfare organization described in Section 501(c)(4) of the Tax Code is permitted to engage in?''

''This is an important issue for health-care providers because there are 501(c)(4) health-care organizations that are going to be stuck with whatever rules or added scrutiny results from the current atmosphere surrounding this issue and because it has contributed to the huge delays in getting the IRS to handle other TE/GE work,'' he said.

Exemption in Danger? Several board members cited a possible increase in pressure on tax-exempt hospitals as the ACA rolls out and said they expected the question of continued exemption of nonprofit hospitals to be renewed in 2014. ''If the patients all move to Medicaid and health insurance exchanges, what of tax exempt status?'' Mark Waxman asked. ''Will there be an ongoing attack on that status for those who do not meet new

and imputed standards? And what role will the IRS really play in enforcing the ACA rules?''

Vickie Brown agreed. ''I look for the nonprofit tax status of hospitals to receive greater scrutiny in the coming year,'' she said. In addition, ''the role of the IRS in the area of health insurance is new and expanded,'' she said, pointing to the fact that ''the ACA tied insurance subsidies and qualification for expanded Medicaid programs to income as well as established possible penalties for noncompliance.''

Michael Schaff pointed to tax implications for physician practices and other providers looking to be acquired as part of the massive restructuring that is going on in health care. ''Certain areas—particularly the anesthesia market space—are seeing a lot of money coming in from Wall Street investors,'' Schaff said. ''Practices that are being acquired need to structure deals, where possible, to maximize the tax benefits by ensuring that the returns for physicians are treated as capital gains rather than regular income.''

9. Labor and Employment. Advisory board members again ranked labor and employment as a top health law issue because of the myriad challenges confronting health-care providers as employers. From regulatory and enforcement actions taken by the Department of Labor and National Labor Relations Board to initiatives pressed by labor unions and the Equal Employment Opportunity Commission, hospitals, long-term care facilities, home health agencies and other institutional providers will have their hands full, they said.

John Doran, Littler Mendelson PC, Providence, R.I., said that ''health-care employers will face significant challenges in 2014.'' He cited wage/hour issues that continue to present challenges for all health-care employers, related whistle-blower actions, and the DOL's changes to the companionship exemption for home care employees.

John E. Lyncheski, Cohen & Grigsby PC, Bonita Springs, Fla., said a pro-union NLRB that continues to press its influence into nonunion issues arising in nonunion workplaces means that provider employers will face increased scrutiny and pressure from board initiatives in 2014.

''The NLRB will have significant impact on employers within the upcoming year and that impact will be inordinate upon the health-care industry because it is so labor intensive,'' he said. ''The NLRB is now back to full strength with a quorum confirmed by the Senate and, thus, a constitutional quorum, but one which is heavily tilted to the side of organized labor.''

''We can expect a continuation of cases intruding deeply into the workplace—such as the social media cases, cases involving confidentiality clauses, and those relating to access to the employees—that have nothing to do with unions,'' Lyncheski said. ''The Board chair takes particular interest in these types of cases and new 'NLRB law' is being made almost weekly.''

''Perhaps the most significant development we can expect at the NLRB is the resurrection of the 'Ambush Election' rule which would shorten the time within which representation elections are held, tie the employer's hands during the process in a number of respects, and otherwise tilt the process in favor of unions,'' Lyncheski said. ''There is now a 3-2 majority on the Board that appears to be in favor of again adopting such a rule and it could very likely be more odious than the last.''

''One of the most interesting issues relates to health-care employers who have insurance plans that run afoul of the ACA's Cadillac plan provisions,'' Lyncheski continued. ''Although not as big of a problem for health-care employers that are union free, for employers who have a bargaining obligation with one or more unions and labor agreements that specify the amount of health insurance coverage, things can get complicated in a hurry.''

''I also expect to see an uptick in union organizing activity as there are numerous indications that SEIU, for one, will be more active in organizing in 2014 and because SEIU covets most significantly employees in the health-care industry,'' Lyncheski said.

Increased Union Activity: Home Health Workers. ''The DOL not only limited the scope of who might qualify for the companionship exemption generally, but specifically excluded those individuals employed by 'third party employers,' in other words, home care agencies,'' Doran noted. ''While the new regulations will not go into effect until Jan. 1, 2015, employers will have to spend time in 2014 determining how to track the time spent by home care employees.''

''By definition, these employees work remotely so determining how many hours they actually work in a week and whether they may be entitled to overtime will present a significant challenge,'' Doran said. ''Coupled with the change to the DOL companionship exemption, many states are making it much easier for home care employees to be organized. As a result, this is a field in which employers can expect to see much more union activity.''

''Although the change to the companionship exemption will only impact a subset of health-care employers, wage/hour issues in general continue to present challenges for all health-care employers,'' Doran said. ''Flowing from this is the continued growth of whistleblower claims by health-care employees.''

Litigation to Watch. Lyncheski noted that the U.S. Supreme Court will issue a decision in *NLRB v. Noel Canning Division of Noel Corp.* (U.S., No. 12-1281) in 2014. The case deals with the legality of numerous recess appointments to the NLRB by the Obama administration and, as a consequence, the validity of many significant decisions of import to health-care employers issued in the past four years. ''Many board decisions could become null and void if the Supreme Court holds the recess appointments were invalid,'' he said.

In addition, ''the NLRB is expected to appeal the Fifth Circuit's recent decision in *D.R. Horton v. NLRB* (2013 BL 335349, 5th Cir., No. 12-60031, 12/3/13) to the Supreme Court for review,'' Lyncheski said. ''I also expect cases concerning the EEOC's guidance on criminal background checks to reach the courts during 2014 and that we will get some indication of whether that guidance will be upheld and enforced.''

10. Corporate Governance. Providers will continue to see governance issues playing a crucial role in determining how well they adjust to seismic change in the health-care industry, board members said, as the need for director awareness of their responsibility for monitoring and addressing complex financial and compliance challenges only gets stronger. Reimbursement,

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Honorable Mention: Provider Pricing

A number of board members identified provider pricing as a continuing health law challenge in 2014, elevating it to honorable mention status.

Health-care market price inflation continues to make headlines and puts the rationale behind provider pricing in serious question, Jack Rovner said. ''If the ACA fails to quell health-care cost increases—such that health insurance is not 'affordable' despite the administration's promises—expect intense further scrutiny of provider pricing tactics and power,'' he said.

Lowell Brown noted that SEIU has announced plans to fund ballot initiatives in California and Oregon that will pressure hospitals to cap executive pay and hospital charges.

According to Gerry Griffith, provider pricing will remain a key issue until the effects of ACA implementation are fully known, because neither the industry nor the government have fully come to grips with the act's far-reaching financial implications.

''This is a huge bet for the health-care industry, and people are just starting to realize how much the model depends on convincing a high number of the so-called 'invincibles' that they should buy health-care coverage,'' Griffith said. ''If they don't, the price goes up for everyone who does buy coverage, which means more people will not be able to afford it and the need for financial assistance policies will increase, as it will in areas with a high number of undocumented individuals.''

Provider and community groups ''are working hard to try to address these gaps, but there are still significant hurdles and unanswered questions,'' he said. ''For example, notwithstanding Secretary [Kathleen] Sebelius' assurances, to what extent will hospitals be allowed to provide premium assistance to patients who face retroactive cancellation of their coverage for nonpayment of premiums?''

''Provider pricing will continue to be an area of both legal and reputation risk because health-care pricing is too complex for anyone to fully understand,'' Richard Raskin said. This complexity leads—fairly or not—to frequent allegations of deceptive, unfair, or monopolistic practices and although everyone knows about this risk, no one has offered a systemic solution that has taken hold.''

fraud and abuse and other provider regulation changes will make being a director ever more difficult, especially as the risk of individual liability continues to rise, they said.

Fred Entin said boards, accustomed to the traditional fee-for-service model, will be challenged by the new combinations of institutional providers, physicians, health plans and ancillary resources that are necessary to care for defined populations. ''The challenge will be to provide insightful leadership to organizations that must exist in two worlds while the industry is in transition,'' he said.

''They must understand that while the organizations they lead must transform into something new and untried, they also need to generate revenue, provide quality care and serve their communities while still living in the current system,'' Entin continued.

''Board education and understanding of new paradigms of care and risk will be extremely important, but may not be enough,'' he said. ''That means, for some systems, that new entities, governed by a board of very different composition, may need to be formed to oversee an evolving organization.''

Michael W. Peregrine, McDermott Will & Emery LLP, Chicago, said providers will need to evaluate the long-term sufficiency of their system's existing governance structure because the traditional nonprofit health system governance model is being tested by the tempo, and the extent, of the health-care reform wave.

''Areas of particular focus will be on board size, director competencies, reporting relationships, and committee structures and extent of delegated powers, with the ultimate question being whether the existing structure assures effective oversight and informed decision-making at the board level,'' Peregrine said.

New Duties, Risks. Peregrine noted that board members ''will also need to demonstrate a significantly higher level of engagement in terms of attentiveness and scrutiny in their exercise of oversight and decision making because the fiduciary standard of care applied to health-care system directors has become more rigorous as the scope of operations, and the value of assets under ownership or control, has increased.''

''The need to deal with new and emerging legal issues internally also may place greater pressure on general counsels, who have a dual role as business partner to management and legal counsel to the corporation,'' Peregrine continued. ''The board and executive leadership must be sensitive to associated ethical challenges and supportive of the general counsel's efforts to resolve them.''

''Although breach of fiduciary duty actions involving health-care system directors continue to be rare events, recent case developments suggest an increased willingness of regulators and other stakeholders to more closely examine director conduct, particularly in controversial matters,'' he said.

Richard Raskin agreed, saying sound corporate governance practices must continue to be a significant priority for health-care organizations. Among many other reasons, the DOJ has taken aggressive steps to apply the responsible corporate officer doctrine to impose personal liability on corporate officers.

Tom Mayo cited ongoing IRS and congressional oversight of nonprofit health-care organization governance as another driving force for ensuring enhanced board of director responsibility and competence. ''The IRS, at the urging of Sen. Charles Grassley (R-Iowa), revamped their Form 990 to make tax-exempt health-care organizations more transparent and to require them to report on a variety of things that fall under the general heading of 'governance,' '' Mayo said. ''Regulatory attention

to health system governance associated with these initiatives will continue to make governance a critical focus for providers.''

BY PEYTON M. STURGES AND MARY ANNE PAZANOWSKI

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