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Outlook 2013

Health Reform Drives Medicaid, Medicare, Fraud and Abuse to Top Ranks for 2013

High-profile provisions of the Affordable Care Act, such as near-universal mandatory health insurance, take effect in 2014. But much of the heavy lifting needed to implement the law enters a make-or-break phase this year, prompting *BNA's Health Law Reporter*'s advisory board to name ***Medicaid***—which plays a pivotal role in health reform—the top health law issue of 2013.

The expansion of Medicaid eligibility to millions more Americans and the challenges faced by the federal government to find ways to encourage states to continue financing services for the needy are just a sampling of the myriad ways Medicaid popped up in board member discussions of the health law forecast for 2013.

''With approximately 15 million new beneficiaries to be added to the Medicaid program, this could become a key driver of state and federal budgets,'' Katherine Benesch, Benesch & Associates, Princeton, N.J., said.

''Medicaid is at the top of the regulatory watch list for 2013,'' according to Richard Raskin, with Sidley Austin LLP, Chicago.

The growing costs of caring for an aging population also ranked high, edging ***Medicare*** to second place on *HLR*'s Top 10 list for 2013. The Centers for Medicare & Medicaid Services ''has much more work to do to implement the Medicare provisions under the ACA, creating new issues of interpretation for health care companies and health care lawyers,'' according to Douglas A. Hastings, with Epstein Becker Green PC, Washington.

The ACA's expansion of enforcement tools, and the fact that ***fraud and abuse*** penalties have become one of the federal government's major mechanisms for sanctioning health care providers of all stripes, guarantees that this area will remain hot in the coming year, board members said, ranking fraud and abuse third on the Top 10 list.

How the ACA will affect who is covered by health insurance and how much coverage they are entitled to, given ACA-driven changes, pushed ***health plan regulation*** to fourth place on this year's list.

According to Jack A. Rovner, with the Health Law Consultancy, Chicago, 2013 easily could be remembered as the year of health insurance reform.

''2013 is the year of implementation and preparation for the 'new' market for health insurance coverage in 2014—with full implementation of the health insurance market reforms, initiation of health insurance exchanges, and flow of federal subsidies to finance millions of new health insurance customers,'' he said.

Health Law Reporter's Top 10 for 2013

1. Funding challenges and Affordable Care Act implementation hurdles put **Medicaid** front and center.
2. **Medicare** program reform issues will figure prominently.
3. **Fraud and abuse** compliance continues to be the biggest source of legal challenges and billable hours.
4. Health insurance reform initiatives make **health plan regulation** a top issue.
5. The push for greater **hospital/physician alignment** permeates nearly all Top 10 issues.
6. Public and private payers look to **quality of care** improvements to control costs.
7. **Health information and technology** grows in importance as regulations are issued and enforcement increases.
8. **Antitrust** issues arise at every turn as markets adapt to health care reform.
9. New compliance challenges keep **corporate governance** on the front burner.
10. **Labor and employment** issues continue to significantly impact the labor-intensive health care industry.

Continuing the past few years' discussions of accountable care organizations (ACOs) and other methods of integrating service providers, board members said 2013 will challenge attorneys to resolve issues surrounding ***hospital/physician alignment***, which came in fifth on the list.

Fredric J. Entin, Polsinelli Shughart PC, Chicago, said such alignment will only intensify this year.

''Much has been written and many have spoken about the inefficiency of the system because of the lack of alignment of the interests of physicians and hospitals. Talk is finally being replaced by action,'' he said.

As federal agencies pump up efforts to use ***quality of care*** as a factor in reimbursements, and as commercial payers look to do the same, providers will be asking their attorneys for advice on how to maximize their returns, according to board members, who ranked that issue sixth on the Top 10 list.

A number of board members predicted 2013 will bring greater compliance demands for a grab-bag of

health information and technology issues that include but are not limited to the Health Insurance Portability and Accountability Act privacy and data security provisions, electronic health records (EHRs), data breach notification, social media, and mobile devices. That issue ranked seventh on the Top 10 list.

Garnering the eighth-ranked spot was ***antitrust***. The push ''for more and more consolidation will ramp up merger and acquisition activity to record levels in 2013 and beyond,'' said Howard T. Wall III, with Regional-Care Hospital Partners Inc., Brentwood, Tenn. He pointed to the ''mad rush of hospitals and health plans to acquire physician practices'' as likely to run squarely into already vigorous Federal Trade Commission and Department of Justice oversight.

Board members ranked ***corporate governance*** ninth on the list. Michael W. Peregrine, with McDermott Will & Emery LLP, Chicago, said this legal issue will continue to be on the front-burner in the health care sector, especially in the face of continued fraud and abuse enforcement pressures, quality of care priorities, and the wave of provider consolidation.

Labor and employment rounded out the Top 10 and ***taxation*** received an honorable mention.

Summing up, Kirk Nahra, with Wiley Rein LLP, Washington, said the Top 10 health law issues for 2013 are ''all pieces of a nationally crucial (and incredibly intricate) puzzle. You can't take one without the other in most of the situations.''

1. Medicaid.

Medicaid will be the No. 1 health law issue for 2013 and beyond, according to an overwhelming majority of *HLR*'s advisory board members. Finding continued funding for the program, as well as implementing changes in coverage eligibility wrought by the ACA, will be a focal point for discussion among attorneys and policy makers in the coming year, advisory board members said.

The ''administration's challenge in implementing the ACA's Medicaid provisions makes this program's future the top issue for 2013,'' according to Doug Hastings. ''The cost challenges presented by providing care to the Medicaid population are daunting, yet the opportunities for achieving both quality improvement and cost efficiency are real.''

''Medicaid will be both a laboratory for change and a huge social and economic obligation,'' he said.

Robert L. Roth, with Hooper Lundy & Bookman, Washington, added that, ''while fraud and abuse always makes for juicy headlines, Medicaid and the health insurance exchanges will affect far more people.''

Paying for Medicaid. Funding Medicaid ''will remain a focal point of health policy debates,'' according to John D. Blum, with Loyola University Chicago Institute for Health Law, Chicago. ''States will be challenged to meet the cost pressures of maintaining current and expanded programs,'' he said. As a result, ''hard negotiations are in store as state agencies, managed care plans, and providers fight over tight dollars.''

''The federal government will be challenged to find mechanisms to encourage states to continue financing services for the Medicaid population when this could mean a decrease or discontinuance of other essential services for state taxpayers,'' Katherine Benesch said.

Health Reform: Driver of All Top 10 Issues

Although the top health law issues included perennial and emerging topics (hospital/physician alignment and health information and technology made first-time stand-alone appearances on the Top 10 list for 2013), the driver behind each topic this year will be the forward movement of the ACA, according to board members.

Echoing the views of most board members, Vickie Yates Brown, of Frost Brown Todd LLC, Louisville, Ky., said that ''many of the anticipated changes in the area of health law will finally converge in 2013.''

''Some of the more monumental aspects'' of the ACA become effective or will be implemented in 2013, leaving ''a lot for the health care industry to assimilate without major disruption to the industry.'' This year, she said, ''will bring about quite an upheaval for the health care industry.''

''Although there continues to be rumbling post-election about repeal of the ACA, implementation is really going to be the issue this year and for the next several years,'' Fredric J. Entin, with Polsinelli Shughart PC, Chicago, said.

With a U.S. Supreme Court challenge put to rest and legislative repeal out of the picture, ''all signs point to 2013 being a watershed year in health law, as the ACA is rolled out in earnest,'' Richard Raskin, with Sidley Austin LLP, Chicago, said.

With those twin obstacles out of the way, J. Mark Waxman, of Foley & Lardner, Boston, said ''it is clear that health reform will move forward.''

Said Raskin: ''This is the beginning of a generational effort that will take years to unfold, comparable only to the introduction of Medicare and Medicaid in the 1960s.''

T.J. Sullivan, of Drinker Biddle & Reath LLP, Washington, agreed. ''The fate of the ACA is settled. Now we only need to wait to see what the states will do with respect to Medicaid and health insurance exchanges.''

In light of these budgetary constraints, ''some states have moved decisively to a managed care model for Medicaid beneficiaries' health care and pharmaceutical benefits,'' Stephanie W. Kanwit, with Stephanie Kanwit LLC, Alexandria, Va., said.

''Expanded eligibility will drive patient volume and place increased pressure on providers to live within financial constraints,'' Richard Raskin added. ''The dark humor behind the old adage—'we're losing money on every case, but making it up in volume'—will be more fitting than ever.''

Howard A. Burde, with Howard Burde Health Law LLC, Wayne, Pa., was more blunt: ''Medicaid is bankrupting the states,'' he said. ''Obamacare simply exacerbates this problem.''

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State Reaction to ACA Expansion. ''It will be very interesting to watch states respond'' to the ACA's Medicaid expansion provision, W. Reece Hirsch, with Morgan Lewis & Bockius LLP, San Francisco, said. While the Supreme Court made clear, in *NFIB v. Sebelius*, 80 U.S.L.W. 4579 (6/28/12), that state participation cannot be mandated, ''it will be very difficult for states to stand on the sidelines, since the ACA provides for 100 percent federal funding for the first three years of expansion costs,'' he said.

Thomas Wm. Mayo, SMU Dedman School of Law, Dallas, agreed. ''Perhaps a few more states will realize that the fiscal and public health benefits of Medicaid expansion far outweigh the political benefits of complaining about a federal takeover of health care,'' he said.

Jack Rovner asked whether ''Republican-run states really can resist implementing the expansion, especially with the federal government paying most of the cost.''

Compromise, Clarification, Reversal? Compromise may be possible, given the ''state-by-state variability and more uncertainty as to the impact of the Supreme Court's ruling on beneficiaries who 'fall between the cracks,' '' Kanwit said. She said there ''is talk of possible limited expansion in some states, and predictions that some states that initially rejected any expansion may eventually succumb to the lure of 'free' federal money—'free' at least until cost sharing kicks in.''

''Watch for possible HHS clarification, per the request of the Republican Governors' Association and others, as to states' ability to choose either partial or phased-in expansions of Medicaid,'' she added.

Medicaid expansion ''may offer the best opportunity in a generation to squeeze costs out of the health care delivery system.''

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

Fred Entin suggested that CMS could persuade states to join in the expansion by making it ''more attractive through the use of waivers and its inherent administrative powers.'' He said that states may ''have significant flexibility to enter into an expanded program and, in a post-election environment, decisions to participate may not reflect the posturing that occurred'' before Obama's reelection.

T.J. Sullivan, with Drinker Biddle & Reath LLP, Washington, said Medicaid expansion ''may offer the best opportunity in a generation to squeeze costs out of the health care delivery system'' by decreasing the use of emergency rooms for primary care. The challenge for the state and federal governments, he said, is to ''do everything they can to make primary care payment rates more attractive'' so that more primary care providers will join the program.

Vickie Yates Brown, with Frost Brown Todd LLC, Louisville, Ky., predicted that the Supreme Court's modification of the ACA's Medicaid expansion provision ''may very well be reversed as states begin to implement a patchwork approach to Medicaid.''

Remaining Questions. Elisabeth Belmont, with MaineHealth, Portland, Me., outlined some of the questions that still surround the ACA's expansion program. For example, can states partially expand their programs and, if so, must the expansion be completed by Jan. 1, 2014? Are states that only partially expand Medicaid coverage, or delay expanding coverage, eligible for at least some enhanced federal funding?

For states that agree to expand their Medicaid programs in accordance with the ACA, is the decision irrevocable? Belmont asked. Can states back out after costs shift back to them?

2. Medicare.

Medicare issues will figure prominently in 2013, according to members of the advisory board. Topping their list is Medicare reform, which, according to Stephanie Kanwit, ''appears inevitable'' and will encompass ''payment and structural reforms of many stripes.'' She said these ''could include higher premiums based on income, competitive bidding, and perhaps an age eligibility increase.''

Doug Hastings agreed. Unless the rate of growth in Medicare costs can be slowed, he said, ''improvements in patient outcomes and patient satisfaction will not be sustainable.''

''Medicare cost growth is at the heart of the long-term federal budget deficit,'' he said.

''As the population continues to age, the explosive costs of post-acute care, and the need to find better ways to coordinate post-acute with acute care, become ever more critical,'' Hastings said. ''Failure to reduce inefficiency and variation in care to Medicare recipients will inevitably lead to greater cost controls and benefit reductions.''

Jack Rovner asked whether ''the program will be altered, regardless of the politically potent and 'entitled' baby boomers coming of Medicare age, to stop our country short of the fiscal cliff.'' T.J. Sullivan seemed to think so. ''One conclusion that seems inescapable,'' he said, ''is that I won't see eligibility on my 65th birthday.'' Another likely change, he said, is ''increased Part B premiums down the road,'' at least for ''high earners,'' despite paying ''higher Medicare taxes now.''

Hospital Bankruptcies Possible? Katherine Benesch said 2013 could see more hospital bankruptcies, given the ''continued imperative that hospitals care for patients without adequate funds to pay the costs of care for Medicare patients.'' The ACA ''contains no reform of the way physicians are paid,'' she said, and ''while the federal government is funding experimental mechanisms for payment based on quality control measures that reflect attempts to find new incentives to reimburse hospitals and physicians, these currently are taking place at a pace that is too slow to solve the payment shortfall.''

Providers could decide to terminate their relationships with patients who fail to follow orders.

—VICKIE YATES BROWN,
FROST BROWN TODD LLC, LOUISVILLE, KY.

Uncovering fraud in the Medicare system may be one way to cut down on Medicare costs, Kanwit said. She said to ''look out for additional emphasis on rooting out fraud and abuse and moving away from the traditional 'pay and chase' model, pursuant to new ACA prosecutorial powers in that area.''

Michael F. Schaff, with Wilentz, Goldman & Spitzer PA, Woodbridge, N.J., agreed, saying: ''Medicare claims will be even more closely scrutinized to further curb abuse of the system.'' He said ''much, if not most, of the Department of Health and Human Services Office of Inspector General's 2013 Work Plan focuses on review of Medicare claims.''

Vickie Brown predicted that ''Medicare will turn to identifying and implementing additional cost saving measures, such as the current 30-day bounce back rule.'' This rule requires hospitals to publicly report when heart failure, pneumonia, or heart attack patients are readmitted within 30 days of being discharged. CMS may pay hospitals with high readmission rates less, beginning in 2013.

''The 30-day rule will likely be the first of many of these types of initiatives which will be implemented by Medicare to achieve cost savings,'' Brown said. ''These types of rules will be the trend rather than massive reimbursement cuts.'' Among Brown's predictions: ''Medicare will intensify its efforts to reduce costs by the use of rules tied to quality of care as justification for nonpayment to providers.'' For example, she said, CMS may identify more ''never events'' to justify nonpayment.

''This will increase pressure on providers,'' Brown noted, adding that it may lead providers to drop patients who fail to follow orders. ''If providers determine that noncompliance by the patient created the situation causing the provider to be in violation of the rules of reimbursement, then providers will be forced to address the issue of noncompliant patients,'' she said. This, she added, could result in ''providers terminating relationships with noncompliant patients.''

3. Fraud and Abuse

Fraud and abuse compliance will continue to be the largest source of legal challenges and billable work for health lawyers and the biggest cause of headaches for their clients in 2013, board members said. Providers will face a changing and challenging compliance landscape and continued pressure from government enforcers and auditors, who should consider the need to exercise restraint, and private sector actors, who have no incentive under the False Claims Act do the same, they said.

Gerald M. Griffith, with Jones Day, Chicago, cited fraud and abuse enforcement as a potent, ongoing concern. ''As a result, providers and suppliers likely will find themselves in 2013 spending more and more time and resources either attempting to bolster compliance programs to avoid fraud allegations, or defending against such allegations when they are made,'' he said.

T.J. Sullivan agreed, saying fraud and abuse will remain a high ranking health law issue. ''As long as ethical concerns and cost pressures continue, congressional and administrative scrutiny and fraud and abuse litigation will continue to grow.''

Citing the enforcement tools expanded by the ACA, Katherine Benesch observed that fraud and abuse penalties have become one of the federal government's major mechanisms for sanctioning physicians, hospitals, home health programs, durable medical equipment providers, pharmaceutical companies, and others for misuse of health care reimbursement mechanisms.

''Armed with an increasing number of laws and regulations, federal and state governments and insurance carriers have beefed up their enforcement offices, and are prosecuting individual and corporate health care providers in record numbers,'' she said.

Disclosure Protocols Working? Sanford V. Teplitzky, with Ober Kaler, Baltimore, Md., commented on the state of voluntary disclosure initiatives, both under OIG's Voluntary Disclosure Protocol and CMS's Self-Referral Disclosure Protocol.

He noted that, while the OIG protocol seems to be working fairly well, there still is a problem with the fact that a submission to the OIG does not result in a release from liability under the FCA.

''In light of the continued emphasis, both by DOJ and the relator bar, on the use of the FCA as the 'sanction of choice,' providers must think long and hard as to whether the OIG's protocol gives them sufficient protection,'' Teplitzky said.

The CMS protocol, meanwhile, suffers from a lack of transparency and negotiation flexibility as well as a tendency on the part of CMS to view all payments based on a noncompliant relationship subject to recoupment even where the services were medically necessary, actually provided, and reimbursed at appropriate amounts, Teplitzky said.

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—KATHERINE BENESCH,
BENESCH & ASSOCIATES, PRINCETON, N.J.

He noted that there have been relatively few settlements under this program, that several submissions were forwarded to law enforcement officials, and that the process by which settlement numbers are determined remains opaque at best.

Aggressive FCA Use. Richard Raskin said he expects fraud and abuse issues to remain in the forefront because ''the DOJ has a long pipeline of FCA cases that

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will easily last throughout the coming year, even apart from new filings encouraged by relaxed jurisdictional requirements.''

Raskin predicted that federal courts will continue to press government lawyers for quicker turnaround on intervention decisions and that relators' counsel will show a ''greater willingness to forge ahead in suits'' in which the government declines to intervene.

Teplitzky cited recent FCA settlements that have drawn into question certain arrangements and factors that have long gone under the radar.

He said he has seen settlements that involve physician employment agreements, under which the government either questioned the validity of the employment relationship, such as in part-time employment situations, or the fair market value of the compensation paid to the employed physicians. ''Thus, simply structuring an arrangement as an employment relationship no longer ends the analysis,'' he said.

''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.

''The bottom line is that DOJ and the relator bar are taking on issues and arrangements that might not have drawn a provider's attention in the past. Thus, it is critical that corporate compliance programs ensure that physician relationships squarely meet applicable Stark exceptions and that, for purposes of the federal antikickback statute, providers ask the 'why' question before the government does,'' he said.

Impact of Consolidation. Toby G. Singer, with Jones Day, Washington, pointed to the significant impact the heightened merger, acquisition, and consolidation activity could have on fraud and abuse compliance and said significant fraud and abuse issues will be in play as regulators are required to deal with the novel arrangements stemming from the physician-hospital integration impetus.

Jack Rovner predicted ''the tension should increase between efforts to structure innovative business arrangements among physicians, hospitals, health insurers, ancillary service providers and others in the health care sector and the fraud and abuse constraints on referral and business capture.''

In the face of complex regulatory and business developments, Teplitzky said, the need for enforcement restraint is as pronounced as ever. ''Regulators need to ensure that the great majority of health care providers, who are doing their best under difficult economic circumstances to promote and improve the provision of high quality health care services at reasonable cost, can do so without having to constantly look over their shoulders for fear that someone with an axe to grind, or a fortune to make, will envelope them in what can be devastating investigations,'' he said.

''There will be a call for the government to be more flexible in enforcement actions and advisory opinions and 2013 may be the year that happens.''

—Toby G. Singer, Jones Day, Washington

Singer agreed. ''There will be a call for the government to be more flexible in enforcement actions and advisory opinions and 2013 may be the year that happens,'' she said.

Kirk Nahra suggested that the fraud and abuse discussion will track the overall approach on health care reform. While the government should be expected to pursue true fraud aggressively, ''what the government needs to avoid, however, is the 'gotcha' mentality of pursuing technical or interpretation violations where there is realistic confusion in the regulations.''

Linking Technology. Nahra said the government's ability to link technology to fraud and abuse through programs like prepay reviews to catch fraud before the claims are paid, will be growing and important. ''This is a way for the government to protect itself without the need for aggressive criminal and false claims sanctions. I also would like to see a renewed focus on appropriate compliance programs, particularly with the government providing reasonable and current guidance to update many of the programs that have grown stale over the past few years.''

Fred Entin agreed, citing the data mining initiatives—to identify areas of waste and abuse—as a recurrent theme in the 2013 OIG work plan, which also identifies numerous areas of concern to the program and provides a ''heads up'' to providers generally about initiatives and priorities.

Michael Peregrine said it will be important to monitor the implications of forthcoming guidance from OIG on its exclusionary authority. ''This is especially the case as it relates to any further clarification of the permissive exclusion authority under Section 1128(b)(15)(A)(ii) of the Social Security Act, the provision that authorizes OIG to exclude an officer or managing employee of an entity that has been excluded or has been convicted of certain offenses,'' Peregrine said.

''There has been substantial industry concern as to whether permissive exclusion remains a credible threat to officers and employees of inpatient health care providers, as opposed to those of pharmaceutical companies, medical device makers, or nursing home providers,'' he said.

Raskin said that he also expects to see continued government use of the responsible corporate officer doctrine to impose sanctions on health care company executives, including those who had no direct involvement in the alleged unlawful conduct.

4. Health Plan Regulation

ACA-mandated state health insurance exchanges—marketplaces where individuals can purchase health insurance that must begin enrolling consumers Oct. 1, 2013, and be fully operational by Jan. 1, 2014—and greater payer-provider integration, spawned by quality

of care and bundled payment initiatives, secured a place on the Top 10 list for health plan regulation.

Plan-provider relationships will continue to be strained by cost-reduction pressures, board members said. While lawsuits brought by providers against plans under the Employee Retirement Income Security Act and state law are expected to continue, much of the action for health lawyers will involve getting payers and providers ready for a radically changed health insurance landscape that is regulated in new ways, they said.

Kirk Nahra noted that health plan regulation, like most of the other Top 10 topics, is intrinsically related to health care reform initiatives and related fallout. ''Private insurance obviously is a critical component of overall health care reform . . . but the fact of the matter is that the line between public and private is blurring—because of the enormous variety of new government programs—and this blurring is only going to continue,'' he said.

''The biggest question over the next few years is whether the health insurance industry will actively participate in this wide variety of new programs, and how the development of new insurance exchanges will affect both the viability of private health insurance and the continued focus of employment as the core element in health insurance coverage,'' Nahra continued. ''A movement away from employer-based coverage will be a fundamental development, and will be a critical element to watch.''

Howard Wall predicted that the formation of health insurance exchanges and the entry of millions of new customers into the health care system, coupled with more public data about provider performance, could produce a new wave of consumerism in health care. Price and quality, in addition to provider preferences, will drive patient decisions about where and when to access health care, he said.

Rules Coming, Challenges Continue. Stephanie Kanwit agreed that the focus now moves squarely to health insurance reform implementation. ''We have already seen a torrent of new ACA regulations, including key rules for the health insurance exchanges and what comprises 'essential health benefits,' '' she noted. ''Specific rules for state health insurance markets—like annual limits, community rating—will shape the rules for all non-grandfathered plans in the individual and small group markets.''

''Watch for possible additional 'tweaks' proposed by some state-based exchanges, such as altering ACA's age-rating bands, set at a 3:1 ratio, to a level more consistent with existing rating bands in many states, such as 5:1. The concern is that younger individuals in states with broader age bands may choose to pay the modest penalty under the ACA rather than buy insurance when faced with the much higher premiums resulting from such compressed age bands,'' she said.

''Watch for possible additional 'tweaks' proposed by some state-based exchanges.''

—Stephanie W. Kanwit,
Stephanie Kanwit LLC, Alexandria, Va.

She also said not to be surprised if the program gets a late start. ''Some delay in implementation of the ACA appears to be inevitable for many reasons, both political and technical, including problems with the computer platform the exchanges will run on. Clearly, many of the state exchanges won't be up and running by January 2014, as envisioned,'' she said.

Kanwit said it also will be interesting to watch whether states avail themselves of innovation waivers provided by Congress in ACA Section 1332.

''The ACA built in considerable 'wiggle-room' for the states under this section, which allows states, starting in 2017, to apply for waivers of many key ACA provisions, including exchange rules, qualified health plan standards, individual premium subsidies, small employer tax credits, and the employer mandate and individual responsibility requirements,'' Kanwit noted.

She also predicted judicial review of assorted ACA provisions in the health insurance realm will continue, notwithstanding the Supreme Court's decision upholding the individual mandate. ''Still 'out there,' in a case soon to be heard by the Fourth Circuit [*Liberty University Inc. v. Geithner*, 4th Cir., No. 10-2347 (remanded from U.S. Supreme Court, 11/26/12)] is the issue of the constitutionality of the ACA requirement that makes most businesses with 50 or more employees provide health coverage or pay a fine,'' she said.

''Other cases to watch include numerous lawsuits challenging the scope of the regulatory requirement under the ACA to provide insurance coverage for contraceptives at no charge,'' she said. Kanwit said she would not be surprised if Congress, given the fiscal challenges it faces, decided to scale back the generous subsidies it granted for ACA insurance coverage.

Will States Be Left on Sidelines? John Blum cited the costs and complexity of organizing and running a health insurance exchange as a challenge that will leave many states on the sidelines. ''Like the situation with Medicaid expansion, CMS will need to be fairly flexible in allowing for various approaches, provided minimum essential benefit targets are met.''

Vickie Brown said the development of health insurance exchanges in 2013 is likely to spur an evolution in the role of state governments vis-a-vis the federal government.

Elisabeth Belmont identified a host of health insurance exchange issues that likely will be in play during 2013. Belmont agreed that, beyond the issues of which states will sponsor exchanges—and how—and whether the federal government will be up to the task of creating exchanges, there are a number of important issues that will have to be worked out.

The first involves the issue of Medicaid eligibility changes and tax credits for purchasing health insurance under the ACA. The others involve the affordability determination with respect to employer-sponsored

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health insurance and the availability of tax credits under federally sponsored exchanges.

Belmont noted that Congress envisioned that expanded Medicaid eligibility would result in health care coverage for many individuals and families with incomes at or below 133 percent of the federal poverty level (FPL) and did not expect that this group would be participating in the exchanges. However, exchanges in nonexpansion states now will have to consider the needs of this population and may face significant pressure to offer economical health insurance coverage to lower income individuals and households.

With respect to the ACA limitation that individuals in the 100 percent FPL to 400 percent FPL range may not obtain a tax credit if their employer offers them minimum essential coverage that is affordable, ''the IRS has been confronted with a thorny issue: should this provision be interpreted in the context of the costs of individual health insurance coverage or in terms of the costs of family health insurance coverage?'' Belmont asked.

''In its final regulations on the tax credits, the IRS did not resolve the issue, defining affordable coverage for the employee in terms of the costs of self-only coverage while reserving the issue as to related individuals for future rulemaking,'' she noted.

Tax Credit Dispute. Finally, Belmont pointed to a dispute over the availability of tax credits for those participating in federally run exchanges as one that could come to a head in 2013. While opponents of national health reform claim that the individual tax credits are only available for insurance purchased in state or regional exchanges run by the states, IRS concluded that making tax credits available to participants in federally run exchanges was consistent with the ACA and congressional intent.

Belmont discounted the likelihood of a successful challenge to the IRS interpretation, saying the ACA adversaries face significant hurdles in establishing standing, clearing ripeness and tax anti-injunction act obstacles, and overcoming the deferential standard of review applicable to the IRS's final determination.

Tom Mayo agreed. ''The question whether federal exchanges can offer subsidies to low-income purchasers seems like an easy one, but it may take some court decisions to settle it.''

5. Hospital/Physician Alignment

The push for greater alignment of hospitals and physicians, to satisfy changing reimbursement models and meet quality of care goals efficiently, is clearly a force that permeates the Top 10 list for 2013 and makes it a stand alone category for the first time.

The spot is well-earned, board members said, as the hospital/physician alignment phenomenon, and the ripples it creates, goes beyond ACOs and influences nearly all of the other Top 10 topics.

Howard Wall called developing new approaches to hospital/physician alignment ''the key element in transforming the health care delivery system'' and observed that physician employment does not equal physician alignment.

''Those systems that figure out a way to engage physicians in the care delivery transformation will be the ones who avoid the fate of the health systems in the 1990s that acquired physician practices with absolutely no strategy about what to do with them once acquired,'' Wall said.

Developing new approaches to hospital/physician alignment is ''the key element in transforming the health care delivery system.''

—HOWARD T. WALL III,
REGIONALCARE HOSPITAL PARTNERS, BRENTWOOD, TENN.

''A major issue in 2013 will be whether legal barriers such as state medical licensing laws, Medicare Part B reimbursement policies, corporate practice of medicine, fraud and abuse laws, and FTC and DOJ restrictions on clinical integration—to name a few—will interfere with the ability of systems to achieve team-based care coordination among affiliated physicians,'' he said.

Gerry Griffith agreed, noting that changes provided for in the ACA, as well as changes in how Medicare/Medicaid and third-party payers in the private sector reimburse providers, will make it imperative for hospitals and physicians to have fully aligned incentives to reduce cost and improve quality of care.

Financial Risks. ''For their part, physicians are faced with the prospect of continual declines in practice revenue despite a continuation or increase in the hours worked and general level of effort devoted to their practices. Without that full alignment, many hospitals and physicians will face substantially increased financial difficulties,'' Griffith said.

''The financial risks associated with these changes in the payment system, and the financial resources required for infrastructure improvements and enhancements to quality of care, such as EHRs, will drive more and more physicians toward hospital employment or other forms of close integration with hospitals and health care systems,'' he predicted.

J. Mark Waxman, with Foley & Lardner, Boston, cited the pressure exerted by enterprises that are not traditional providers of health care as an added force to realignment. ''Who is a true market expanding and reshaping provider? Is it Costco or Wal-Mart? And what changes will they make, and force others to make?'' he asked.

Dawn R. Crumel, with Children's National Medical Center, Washington, said physician practice acquisition activity has increased over the last year, placing a significant burden on hospitals entering into these arrangements. ''These acquisitions require hospitals to undertake a very measured and deliberate review of affiliations to ensure alignment with health system strategic goals,'' she said.

Waxman also noted that provider alignment will be geared to go well beyond the need to respond to reimbursement changes imposed by government payers. ''Providers who are involved or exploring MSSP [Medicare Shared Savings Program] ACOs clearly will not stop with the Medicare program.

Big Driver of Real Change. According to Katherine Benesch, ''The dramatic change in physician/hospital alignment is one of the biggest drivers of real change in the health care system and one of the most creative and

challenging areas of health law today.'' Hospital/physician alignment ''is currently in flux with multifaceted models as numerous as health lawyers and physicians can conceptualize and implement,'' she added.

''While specialty physicians in the past were almost all independent operators, who worked as members of the hospital medical staff and who were able to call the shots as they directed patients into the hospital and controlled major sources of hospital revenue, this is no longer the case,'' she said.

Potential Pitfalls. Mark A. Kadzielski, with Fulbright & Jaworski LLP, Los Angeles, agreed that the realignment of physicians with hospitals will continue in 2013, but said that the road will not necessarily be a smooth one, as the goals of alignment intersect with the needs of medical staff and credentialing managers.

''For those of us who have been around for more than a few years, the ebb and flow of such alignments are nothing new. Indeed, while hospitals and physician groups are busy bundling and repositioning, the traditional medical staffs at hospitals are undergoing changes as well, particularly concerning the expansion of hospital privileges for hospitalists and nonphysician practitioners,'' Kadzielski said.

''Among the key issues related to the formation of ACOs are credentialing and peer review of individual practitioners affiliated with these new organizations. At the outset, there is a rush to sign up lots of physicians and nonphysician practitioners in an effort to 'capture' market share, however defined,'' he said.

Kadzielski said he is concerned, however, that there is little, if any, focus on credentialing or screening to ensure that only the highest quality practitioners are included and that, as practitioners are found to be cost and/or quality outliers, ACOs will seek to jettison them for economic reasons. ''At that point, the potential for expensive litigation will be great,'' he said.

Impact on Physicians, Patients, Payers. Michael Schaff pointed to the driving forces for physicians looking to more closely align with hospitals and the choices they will need to make in doing so. ''In light of the uncertainty surrounding the regulatory and reimbursement climate of health care, physicians must make key business decisions about the future of their medical practices,'' he said.

''Due to this changing health care environment, physicians will be considering selling their practice to hospitals and transitioning from owner to employee as this alignment offers physicians the stability of a consistent paycheck and access to sophisticated health information technology systems that few can afford to acquire and manage on their own,'' Schaff said.

''Physicians will be considering selling their practice to hospitals and transitioning from owner to employee.''

—Michael F. Schaff, Wilentz, Goldman & Spitzer PA, Woodbridge, N.J.

Some, however, may pursue an alternative approach under which they lease their practices and enter into professional services agreements. ''This alternative has many benefits for the physician practice, including leveling the playing field between the hospital and the practice when the time comes to renegotiating the compensation arrangement,'' he said.

Eric A. Tuckman, with Strategic Health Advisors, Coto de Caza, Calif., observed that the health care industry, in the past few years, has seen the creation of institutionally based large professional and physician management organizations that either employ or contract with physicians. ''This concentration of professional services in one organization will give rise to challenges by those who have been excluded or prevented from participating, as well as from competing organizations who will assert that the business practices of these integrated entities amount to anticompetitive activities or unfair business practices,'' he said.

''As some of these alignments undoubtedly unravel we are likely to see contractual disputes over ownership of the lives being supported/covered, as well as enterprise valuation issues concerning the value of the component parts of the dissolved entity,'' Tuckman added.

6. Quality of Care

Quality of care is a ''longstanding issue in health care,'' according to John Blum, that will become even more important in 2013. As Katherine Benesch noted, ''quality of care has become the touchstone for cost control in the new health care system. As such, it is becoming a major driver to help rationalize payment or nonpayment for services rendered.''

''The challenge,'' Benesch said, ''is to develop accurate data points that truly reflect quality service for specific treatment modalities in particular circumstances and populations, and not to rely on quality measures simply because they are easy to ascertain.'' Benesch said there are rumors ''that payment already is being denied on the basis of criteria that are too simplistic, and do not adequately reflect the patient populations at specific types of hospitals.''

''The concept of tying payment to quality in an attempt to reduce the cost of care is a good one,'' she said. But it ''must be implemented in a manner that makes sense for the type of institution and patients affected.''

As far as physician payments are concerned, Benesch said physician behavior must change. To accomplish this, ''value-based bonus payments must be meaningful, and at present, they are very modest,'' she said. ''In addition, physicians must be trained and re-trained to understand these criteria, and how to work with them. Otherwise, the desired effect of this shift in paradigm will not be achieved.''

Shifting Paradigm. Gerry Griffith said the ''paradigm for payment for health care services'' now includes ''a strong movement toward payment for the quality, rather that the quantity, of the services provided.''

Griffith said he expects ''to see continued growth in quality incentive programs from private third-party payers, gainsharing programs through demonstration projects or otherwise, and other pay-for-performance programs.'' He said these changes ''will require rethinking and redesign of existing hospital-physician relationships and require new ways of thinking about the delivery of care and what constitutes a successful care delivery paradigm.''

Stephanie Kanwit noted that ''everyone recognizes quality deficits in health care, including over- and

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under-utilization, as well as disparities in care and unexplainable geographic variation.''

Improvements that are needed, Kanwit said, ''include provider performance standards based on collection, measurement, and analysis of actual data; more emphasis on patient-centered care, such as self-management tools for patients and value-based designs; and, of course, more reliance on sophisticated health IT systems and data registries that allow better use of data.''

Michael Schaff pointed out that ''2013 will be the first full calendar year of the new hospital value-based purchasing program, under which value-based incentive payments will be made to hospitals that meet certain performance standards during the fiscal year.'' Schaff said ''this is one of the most prominent new quality of care initiatives brought on by health care reform.''

Responsibility for Improvement. As to who is responsible for improvements in quality, Michael Peregrine said that ''governing boards and their quality committees will be expected to assume increasing oversight responsibility for the quality of care provided in their institutions.'' Peregrine suggested that the ''structure of quality committees should reflect the value of lay board member participation and the useful contributions of both medical staff professionals and, where appropriate, medical ethicists.''

Dawn Crumel added that ''there is an ongoing cultural shift from the top of the organization to ensure closed loop communication, peer checking, peer coaching, and validation and verification to reduce error.''

7. Health Information and Technology

Long overdue health care privacy and security regulation, combined with ramped up enforcement and new compliance requirements pushed health care technology and health information onto the Top 10 list for the first time.

''A number of trends are converging that will serve to bring health information issues front and center in the coming year,'' Reece Hirsch said.

''In 2013, the regulatory landscape for privacy and security compliance will continue to evolve as health care providers expand their usage of EHRs, portable media and mobile health technologies, as more clinicians utilize social media, and as more protected health information (PHI) is disclosed as a result of increased reliance upon business associates without adequate oversight, thereby increasing the potential for unauthorized exposure of PHI,'' according to Elisabeth Belmont.

As a result, ''health care providers can expect heightened regulation . . . and enforcement of the privacy and security requirements under HIPAA/HITECH and its implementing regulations as well as under other state and federal health privacy laws,'' she said.

''Health care providers can expect heightened regulation . . . and enforcement of the privacy and security requirements under HIPAA/HITECH.''

—Elisabeth Belmont, MaineHealth, Portland, Me.

Leading the list of top regulatory health care technology and information issues is the anticipated end in early 2013 to the long wait for the release by HHS of its final omnibus rule, which includes changes to the HIPAA Privacy Rule and Security Rule, as required under the HITECH Act; a final version of the HIPAA breach notification rule; and updates to HIPAA's enforcement regulations. Also expected is a final accounting of disclosures rule.

In addition, Stage 3 of the HITECH Act meaningful use program, set to be finalized in 2013, could include requirements for providers to conduct a health IT safety risk assessment.

''The administration has to issue these rules in 2013,'' Kirk Nahra said. The delay ''is itself causing problems. There is no reasonable excuse for taking this long,'' according to Nahra.

''With that said, we also can hope that the rules will match the HITECH law relatively closely, without getting into new and unexpected areas that were not part of the proposed rules.''

Breach Notice: Meaningful Changes to Rule? Nahra said a key point to watch is whether there will be ''meaningful change to the breach notification rule.''

The interim final breach notification regulation requires HIPAA-covered entities to notify individuals of the breach of unsecured protected health information. Notification also must be given to the secretary of health and human services, with deadlines for notification dictated by the size of the breach, and business associates must notify covered entities of breaches.

Based on ''the experience to date, there is no obvious reason to change the rule,'' as breaches are being reported and individuals are being notified, ''even in many situations where the actual risk of harm'' posed by the breach ''is quite small,'' Nahra said.

A major issue that remains, he said, is ''how far downstream the HIPAA business associate requirements will flow, particularly for full compliance with the HIPAA Security Rule. HHS should impose a 'reasonable and appropriate' standard on downstream entities, rather than full HIPAA compliance.'' He added that business associates will need to be ''in full compliance with the HIPAA Security Rules'' seven months from the date of publication of the rule. ''This is a significant challenge, and one where business associates should start now on these efforts,'' he said.

When the final regulations are released, ''many business associates and their subcontractors will be scrambling to achieve compliance with the HIPAA Security Rule,'' Hirsch added.

Uptick in HIPAA Enforcement. Noting that the first wave of audits by HHS's Office for Civil Rights for compliance with the HIPAA Privacy and Security Rules has been completed, Hirsch said to ''expect the pace of HIPAA enforcement actions to further accelerate, including actions by state attorneys general.''

Pointing to continued OCR privacy and security enforcement activity in 2013, Belmont said settlements that occurred in 2012 ''indicate renewed interest at HHS in enforcing violations of the HIPAA Security Rule, which, for many years, was secondary to Privacy Rule enforcement.''

Data from OCR show that ''most of its enforcement cases involve the following three types of violations: (i) theft of data or data storage devices (e.g., USB drives or laptops), (ii) unauthorized access/disclosure of data, and (iii) loss of data or data storage devices. These are

the types of violations that typically arise when an organization has failed to implement appropriate security safeguards,'' Belmont said.

Cloud Computing, Mobile Devices, Social Media. Privacy and security issues, such as emerging standards for cloud computing and the use of so-called Big Data, are affecting all businesses more and more, but ''will increasingly impact health care companies,'' Hirsch said.

Noting that OCR released guidance Nov. 26, 2012, on how health information may be de-identified, Belmont said that in 2013, ''Covered Entities and their business associates will expand their uses of de-identified health information to reduce their exposure to HIPAA/HITECH violations and to expand their use of health data, including the sale of such data to third parties.''

Studies have shown a rise in the use of smartphones and tablets for health information, Belmont said. As a result, health care providers ''will need to address . . . regulatory hurdles including privacy and security of patient data, compliance with state and federal laws (including Stark and anti-kickback statutes), assumption of risk and liability, along with other critical issues relating to EHR usage which should be addressed in the vendor agreement,'' she said.

In 2013, according to Belmont, ''we can expect to see more mobile EHR apps which will present an increased compliance burden for the provider organizations and individual practitioners who utilize them.''

2013 also will bring heighten social media risks, Belmont said, ''as more physicians and health care organizations move to social media to communicate with patients and promote health care services, thereby increasing the risk of unauthorized exposure of PHI.''

''Health care organizations and providers need to carefully review their social media policies and ensure that all clinical personnel and other staff are familiar with such policies in 2013,'' she cautioned.

Added Pressure on Top Hospital Brass? Vickie Brown predicted that 2013 will bring ''added pressure on the hospital 'C' suite [including CEOs, CFOs, CIOs] as hospital administrators begin to review their return on investment for the enormous amount of money they have spent on health information technology.''

Brown added that there is a ''crisis around health information exchange, and achieving meaningful use of EHRs.'' That crisis extended to ''forcing providers to implement health IT before the technology industry could properly deliver products to achieve needed results. Lots of promises were made to hospital CEOs and others that IT products could deliver certain savings and achieve certain deliverables.''

Now, Brown said, ''payments have begun and the reality of whether the deliverables will live up to the promises will occur in 2013. Legal actions in this area will likely result from providers seeking redress based on breach and disappointing return on investment.''

8. Antitrust

Alignment, merger and acquisition, consolidation—call it what you will, board members said. It will be in full swing in 2013.

Richard Raskin predicted 2013 will be an exceptionally active year in health care antitrust. ''We have every reason to believe that consolidation among providers, health systems, and insurers, already occurring at a fast clip, will accelerate further in light of ACA roll out.''

While this will cause the FTC and DOJ ''to face a huge volume of health care transactions—some reportable, some not—from mergers of national for-profit entities to hospital acquisitions of local physician practices to formation of ACOs, the creation of larger regional and national systems could lead some of these providers to take on the challenge of fighting back threatened enforcement activity,'' he said.

Expect continued antitrust activity as the industry continues to consolidate in response to health care reform and market conditions.

The real, and so far unanswered, question is whether consolidation in health care lowers or increases health care costs, Howard Wall said. ''Although some recent studies suggest that health care consolidation does not lower costs, in most other industries that experience massive consolidation, costs to the consumers are eventually lowered.''

Most industry observers, he continued, believe that consolidation should lead to increased efficiencies and elimination of costly duplication that in many markets drives up costs. ''2013 will be an extremely important year as the only thing that might put the skids on the prediction of a record year in health care M&A might be a vigorous antitrust enforcement agenda that could discourage market consolidation efforts,'' Wall said.

Toby Singer also said that antitrust will continue to be active as the industry continues to consolidate in response to health care reform and market conditions that challenge smaller and independent health care systems.

''Both federal agencies and the state AGs will continue to be aggressive in challenging provider and health plan consolidation,'' she predicted.

''While the FTC will focus more and more on physician transactions in addition to hospital affiliations—we have now seen private litigation in that arena—look for private litigants to continue to be active, particularly in follow-on litigation to government actions, such as the MFN [most-favored nation clauses] litigation against Blue Cross Blue Shield entities,'' Singer said. ''We will also see new leadership at both federal antitrust agencies, but do not expect a change in direction; the new appointees will continue to pursue the same policies.''

Balancing Act by Regulators. Doug Hastings said regulators will have to conduct a balancing act that asks whether integrated delivery and care coordination, notwithstanding quality improvements, inevitably lead to abuses of market power. ''While I believe that the answer is 'no,' this question remains at the heart of an important policy debate that is front and center in Washington and around the country,'' Hastings said.

''There is potential for new forms of contracting and joint ventures—rather than mergers—among competing providers, working with payers, to accomplish accountable care goals through bundled and global payments to create antitrust-acceptable pathways, such as one utilizing payments based on measurable value,'' he

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said. ''The private sector would benefit from greater payer-provider cooperation in this regard.''

''Failure to do so will put more onus on government to regulate the prices of both and to micromanage the contracts between them. Therefore, payers and providers would be well served to adopt voluntary protocols relating to quality measures and cost efficiency, and to allocate savings between them and with purchasers and consumers,'' Hastings said.

Market Consolidation, Continued Tension. Mark Waxman said that market consolidation is for real. ''We continue to see acquisitions, large and small, between hospitals and hospitals, health plans and health plans, physicians and both hospitals and health plans,'' he said.

''The market is clearly going through a significant change, but how that will reshape health care delivery continues to unfold,'' he said. ''However, the recent renewed antitrust-based attacks, both by the FTC and by private parties, on mergers and acquisition activity, provide one clear sign of how it is likely to unfold.''

T.J. Sullivan said he expects provider consolidation and integration to accelerate once the economic uncertainty around taxes and the economy are clarified. John Blum, however, queried, ''Just how much of a 'pass' will ACOs really get?''

Douglas Ross, with Davis Wright Tremaine LLP, Seattle, cited continued pressures for consolidation across the industry and the ''continued tension between the forces driving consolidation among hospitals and physicians—including the need to respond to reform and the capture the substantial scale efficiencies in costs and clinical care available to larger and integrated systems—and the FTC's view that stand-alone community hospitals remain a viable competitive model.''

Roles Blur as Insurers Acquire Providers. While Ross said he expects the government to investigate and possibly challenge physician acquisitions by hospitals and physician consolidation, the FTC's ability to do so may be compromised somewhat by its settlement of the *Renown Health* case in Reno, Nev. [*In re Renown Health*, FTC, No. 1110101, *proposed consent order filed* 8/6/12]. ''Having agreed there that releasing doctors from noncompetes is a sufficient solution to consolidation, how can the agency take a different position elsewhere?'' he questioned.

''We continue to see acquisitions, large and small, between hospitals and hospitals, health plans and health plans, physicians and both hospitals and health plans.''

—J. Mark Waxman, Foley & Lardner, Boston

Ross also pointed to the Supreme Court's expected decision in *FTC v. Phoebe Putney Health System Inc.* (No. 11-1160, *argued* 11/26/12)—and the FTC's continued hostility to the state action doctrine—and continued investigations and possibly litigation involving health care system contracting practices as important focal points for health care antitrust lawyers in 2013.

Eric Tuckman said that ''hospitals and health systems have reacted aggressively to the blurring of traditional roles resulting from insurers acquiring providers such as large medical groups and institutional providers.''

In response, ''many of the large national and regional health care systems have or are actively considering entering into the insurance business through the acquisition of existing insurance companies or the formation of new commercial, Medicare Advantage or Medicaid plans. This actively will continue in 2013—perhaps even at a faster pace,'' he continued.

More Aggressive FTC Role? In the face of these changes, FTC is expected to continue to take a much more aggressive role with regard to hospital and physician organization mergers, Tuckman said.

''We also are almost certain to see increased scrutiny from government regulators including state AGs as the large regional systems expand across state lines to form 'Super Regional' integrated physician delivery networks. The evolution of these integrated delivery networks into both provider and insurance companies will likely necessitate new regulations to assure fiscal solvency and operational viability,'' Tuckman said.

''Also, as bundled payments and risk-based contracting become more prevalent and with the proliferation of narrow network contracting by large integrated systems, questions relative to predatory pricing will arise,'' Tuckman continued. ''The complexity of these arrangements and the lack of industry experience with risk-based and capitated arrangements will camouflage some of these unlawful practices but entities who are excluded from these networks are likely to challenge the underlying pricing practices as schemes to illegally grab market share.''

Gerry Griffith cited antitrust issues associated with consolidation as a primary concern in 2013 while pointing to hospital realignment, in particular, as an important subset of this regulatory and legal practice area. ''As more and more hospitals affiliate, there will be more opportunities for the antitrust regulators to challenge the affiliations as potentially anticompetitive,'' he said.

''The trend toward increased antitrust enforcement for health care transactions is likely to both increase transaction costs and increase uncertainty as to whether deals can proceed, on what timetable, and whether they will be subject to challenge after-the-fact,'' he said. ''Given the sheer volume of deals that are likely, we may see more of these cases brought after-the-fact, particularly for hospital/physician transactions.''

''Just as physicians find their financial livelihoods threatened, so too do many stand alone hospitals. Even hospitals that are currently on sound financial footing may be feeling the need to affiliate with other hospitals or larger systems in order to preserve the long-term financial viability and mission of the institution,'' Griffith said. ''As a result, there are likely to be significantly fewer stand-alone community hospitals in the years to come, with an increasing consolidation of hospital services, both inpatient and outpatient, in fewer regional or national systems.''

9. Corporate Governance

Hospitals and other institutional providers face compliance issues on all fronts, from reimbursement and

quality to fraud and abuse and tax-exemption. Those forces will, of necessity, increasingly demand more involvement by better qualified and engaged corporate board members, advisory board members said.

The high stakes for the corporation, and even a threat of personal liability for corporate executives in the event of noncompliance, will make it all the more critical that health care reform's implications for corporate governance be heeded, they added.

Michael Peregrine cited a series of governing board-focused concerns. ''First is a question of the time and attention commitment required of governing board members. Second is a question of the appropriate size of the governing board of the new, larger system. Third is the question of the emerging qualification expectations of governing board members. Fourth is the importance attributable to clarification of the roles and responsibilities of the system governing board and of the various affiliate boards,'' he said.

''Another important fiduciary issue is the continued potential for intra-system disputes between affiliated corporations based on allegations of a breach of duties the parent may be perceived as owing to the affiliate entity. The 2012 decision in the Sutter Health/Marin Healthcare District arbitration proceeding highlights a different interpretation of the legal question of whether a parent indeed owes fiduciary duties to the affiliates,'' Peregrine continued.

''The emphasis on post closing covenants in many of the popular 'cashless' nonprofit affiliations increases the focus on this issue. Nonprofit parent corporations and their legal counsel, therefore, should carefully review affiliation agreements and corporate governance structures to evaluate the potential for such risks,'' he said.

ACA-Driven Challenges. According to Doug Hastings, corporate governance remains a Top 10 issue because health care provider organization boards, as fiduciaries, face a variety of new challenges in the accountable care era. ''The last decade has brought greatly increased scrutiny of the duty of care and the duty of loyalty expected of corporate board members, requiring them to be active and knowledgeable in their oversight,'' he said.

''Corporate directors will need to address the following concerns, among others: fee for service payments are likely to decline in the years ahead, challenging financial performance; additional payment changes will further reduce reimbursement to providers with poor scores on quality measures or who evidence inefficiencies such as above average readmissions; and the shift to various forms of bundled and global payments will require infrastructure investments by providers that may or may not be reimbursed, further threatening financial solvency,'' Hastings said.

Health care provider organization boards, as fiduciaries, face a variety of new challenges in the accountable care era.

—Douglas A. Hastings,
Epstein Becker Green PC, Washington

In addition, ''boards will be faced with the fact that the increasing focus on quality measurement and reporting may trigger fraud and abuse enforcement against providers making payment claims to public and private payers for care subsequently deemed to be substandard, and will need to realize that greater quality data reporting and transparency will require greater board oversight to ensure that reporting is accurate, and compliance plans will need to be enhanced to address these expanded concerns,'' he added.

Katherine Benesch agreed that corporate governance has taken on increased importance for health care provider organizations. ''The past few years have seen the federal government continue to prosecute and sanction individual members of hospital governing bodies for lapses in oversight and/or participation in fraudulent payment schemes to increase reimbursement into corporate health care coffers and into the pockets of individuals,'' she said. ''This reflects a philosophy that it is not enough to sanction the institution itself, if individuals can continue to carry out illegal or questionable activities, after their entity has been prosecuted.''

In addition, ''governing bodies are responsible for an organization's corporate compliance programs, which serve as tools for prevention of fraudulent activities, as well as important components of the corporate integrity agreements institutions enter into with the government after a settlement of an alleged violation of fraud and abuse laws,'' Benesch added.

Finally, corporate governance ''is extremely important in the successful implementation of new joint venture models of networks between and among health care systems, physician groups, ACOs and others. The governance structure must include in a meaningful way many varied stakeholders in the health care system, and can 'make or break' the successful implementation of the endeavor,'' she concluded.

Threats Abound. Peregrine said he sees threats that demand substantial board competence and preparation across the full range of health care compliance challenges.

In the fraud and abuse arena, for example, ''the increasing Stark and anti-kickback enforcement activity of the federal government on major physician/hospital transactions increases the oversight obligations of health system compliance committees and governing boards,'' he said. ''It also increases the value of having clear transaction oversight guidelines that incorporate criteria that demand a full examination of legal issues and related risks associated with transactions.''

Governance issues also permeate the use and adoption of health technologies because of the importance to the organization of technology acquisition, privacy matters and compliance, and cybersecurity, he said. ''It is

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increasingly paramount that technology issues be subject to the oversight and attention of a dedicated committee of the governing board and that the board actively solicit new board members with expertise in technology items so as to assure the board has competence in this arena,'' Peregrine added.

10. Labor and Employment.

Labor and employment issues will continue to significantly impact the health care industry, as union organization initiatives and ACA implementation proceed. Several board members suggested that for some hospitals and systems, labor issues will be a major focal point that distracts them from their core health care delivery missions.

According to board members, union organizing campaigns, pending health care/labor court cases, continued pro-labor agencies and regulations, employee use of social media, and employee benefit issues will require health care employers to closely monitor the labor and employment landscape.

A number of significant issues involving the National Labor Relations Board are likely to be decided in 2013 at the federal appeals court level, John E. Lyncheski, with Cohen & Grigsby PC, Bonita Springs, Fla., said. He pointed to cases involving the NLRB's new notice posting requirement, the election rule ''which is affectionately referred to as 'the ambush election rule' by many, and the legality of the NLRB recess appointments and, as a consequence, the viability of all of the decisions issued involving the recess appointees in question.''

With respect to the Equal Employment Opportunity Commission and the Department of Labor, ''as a result of the election outcome, we can expect even more aggressive enforcement of the laws and regulations already on the books and the issuance of new regulations and guidelines such as the recent EEOC guidelines applicable to criminal background checks,'' Lyncheski said. ''There will also likely be continued efforts to subject more health care employers to the affirmative action requirements of Executive Order 11246 based upon whatever thread of funding or revenue that can be traced to a government 'contract,' '' he added.

Doug Ross agreed the sector could be faced with challenging employment issues in 2013. ''Mandatory vaccinations and similar mandatory 'invasions' of employee privacy will be an interesting issue to watch,'' he said. Ross also cited ''the evolution of intermediate care facilities as a phenomenon that may bring with it issues, such as whether they should be treated like acute care facilities under the NLRB's presumptive units rule.''

''We also can expect the NLRB to continue its efforts to extend its reach into areas having nothing to do with unions and organized labor such as it is now doing with employer social media policies—and employees disciplined under those policies—and as it has done in questioning historically cookie cutter employment policies such as those limiting off duty access and requiring confidentiality in a number of contexts,'' he continued.

''We also can expect the NLRB to continue its efforts to extend its reach into areas having nothing to do with unions and organized labor.''

—Douglas Ross,
Davis Wright Tremaine LLP, Seattle, Wash.

''Expect more and more employee friendly—employer unfriendly—decisions to be issued in those areas and in attacking the application of other employer and handbook policies that, heretofore, never have been a problem.''

Social Media: Flashpoint. Elisabeth Belmont said that the social media issues exploding into the employment arena are unlikely to spare health care employers.

''In 2013, health care employers can expect increased regulation regarding the use of social media in the workplace,'' and, in keeping with recent NLRB decisions and guidance memoranda from its acting general counsel that employer social media policies may not chill protected activity under Section 7 of the National Labor Relations Act.

Pending Cases. Lyncheski pointed to two pending Supreme Court cases of significant interest to health care employers. The first is *Vance v. Ball State University* (No. 11-556, *argued* 11/26/12), which deals with the issue of who might qualify as a supervisor for purposes of employer liability under the federal antidiscrimination laws. ''The high court is being called upon to decide what level of alleged responsibility for another employee's work would be sufficient to make that employee a supervisor for purposes of Title VII of the Civil Rights Act,'' Lyncheski said.

''It involves a claim that another employee, who, for all intents and purposes, was an employee of similar 'rank' was a supervisor for whose acts the employer was responsible and who had subjected the plaintiff to a hostile environment based on her race,'' he said. If the individual is a supervisor, vicarious liability would attach, he noted.

''This case is extremely significant to health care providers because of the extent to which supervision in hospitals and other health care facilities is decentralized and because of the large number of individuals who might fall under the definition of supervisor and subject their employer to vicarious liability for their actions if the court adopts a liberal standard,'' he said.

The second Supreme Court case of significance to health care providers, which the justices considered in a Dec. 3, 2012, oral argument, is *Genesis Healthcare Corp. v. Symczyk* (No. 11-1059). ''The issue in this case is whether, when an employer defendant in an Fair Labor Standards Act case offers to pay the named plaintiff for his or her claim in full, this terminates a case brought as a 'collective' action under the act,'' he noted.

''The outcome of this case is important because health care facilities of all types are subjected to an inordinate number of FLSA claims and almost all are filed as collective actions,'' he said.

Benefits, Other Challenges. On the benefits side, while acute care hospitals will not be impacted disproportionately by the ACA, they will be significantly impacted by what is expected to be a flood of regulations under the act because health care delivery is so labor intensive, Lyncheski said.

''Almost all acute care hospitals already offer health insurance coverage which satisfies the ACA's mandates, but it will be somewhat of a different issue for long term care facilities, many of which do not now provide qualifying health care coverage, but which employ sufficient employees to be subjected to the mandates,'' he said.

Belmont said wellness promotion programs could be another potential compliance challenge for employers during 2013, citing proposed regulations federal agencies issued in November 2012.

''Because the proposed regulations apply to both grandfathered and nongrandfathered plans in both the insured and self-insured markets, and are effective for plan years beginning on or after Jan. 1, 2014, plan sponsors and issuers in 2013 need to review their current wellness programs given the proposed regulations and, once the final regulations are published, make any necessary changes to comply with the new regulations,'' she said.

Honorable Mention: Taxation

Taxation issues in the exempt hospital sector will continue to challenge these organizations and their counsel as the Internal Revenue Service moves ahead with implementing ACA provisions and as reporting and filing deadlines contained in the law kick in, board members said.

This year will be particularly challenging as hospitals will be required to move ahead with what most agree is insufficient or, in some cases, conflicting IRS guidance on how it expects this sector to comply with critical ACA requirements.

''The IRS has been working overtime to provide ACA guidance, but, unfortunately, provider tax exemption issues are only a small part of what the IRS and Treasury Department are grappling with,'' T.J. Sullivan said.

On the regulatory front, Sullivan said he expects to see proposed IRS regulations setting forth standards for community health needs assessments required of hospitals under Section 501(r) of the code. ''Providers are hoping that the IRS looks to experience under New York and California community health needs assessment laws that have been in place for over 15 years,'' he said.

With respect to other 501(r) requirements imposed on tax-exempt hospitals under the ACA, Sullivan noted that the IRS received ''robust comments on proposed regulations which likely will lead to some easing of the requirements while keeping their spirit intact.''

''One interesting development to keep an eye on is the resurgence of interest among for-profit chains in participating in mergers or joint ventures with not-for-profit hospitals. Another is a likely explosion of interest in proton beam therapy center deals,'' he said

Hospitals will be dealing with conflicting IRS guidance on how it expects them to comply with critical ACA requirements.

Eric Tuckman predicted that the radical reduction in the number of uninsured patients as a result of health reform will cause a further reexamination of the basis supporting the tax-exempt status of many providers. ''It is likely we will see an increasing number of states and localities adopting policies and practices implementing some form of payment in lieu of taxes to justify continued favorable tax treatment or as a condition of granting discretionary approvals,'' he said.

Scrutiny Guaranteed. Gerry Griffith suggested that tax-exempt providers should not lose sight of IRS's enforcement and revenue generation role and agreed that exempt providers will continue to be the focus of scrutiny concerning activities undertaken to benefit their communities and needy patients. ''Just as fraud and abuse enforcement generates money for the fisc, so too do audits and other IRS activities,'' he said.

The ''ACA does not in fact cover all of the uninsured or underinsured,'' Griffith noted. ''Therefore, nonprofit hospitals will continue to face significant pressure to justify exemption through charity care and other substantial community benefit activities.''

''Part of this process includes a review by the IRS of hospitals' activities to assess and address the health care needs of the communities they serve. These reviews will be a regular occurrence, happening once every three years, for every nonprofit hospital,'' he said.

''Although the reviews may be in the form of a review of the filed Form 990, rather than a full-scale audit, any questions revealed by that review could lead to a full audit of the hospital. The consequences for failing to meet the community health needs assessment and other requirements in section 501(r) can be extreme,'' Griffith continued. ''The IRS recently issued proposed regulations implementing certain aspects of these new requirements for nonprofit hospitals, and we can expect further rules from the IRS on the consequences of noncompliance during the coming year or soon thereafter,'' he predicted.

''The IRS also is likely to continue its close scrutiny of compensation matters, including executive compensation and potentially physician compensation, for potential excess benefit. In addition, learning from its experience in reviewing the unrelated trade or business activities of colleges and universities, the IRS is likely to explore ways to audit the unrelated trade or business activities of health care organizations without doing a traditional on-site examination,'' he continued.

''Through the use of compliance checks and correspondence exams, the IRS may end up raising significant revenues from some health care organizations by reviewing unrelated trade or business activities and imputing profits, challenging allocations, or otherwise increasing the tax bill for otherwise exempt organizations. As in the fraud and abuse enforcement area, this trend will translate into the need for additional re-

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sources devoted to tax planning and compliance activities, as well as defense of potential assessments from the IRS,'' Griffith said.

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