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Fraud Enforcement Top Health Law Issue As Industry Faces Reform's Uncertainties

The convergence of regulatory and compliance challenges driven in large degree by the Patient Protection and Accountable Care Act (PPACA), an entrenched and aggressive government enforcement stance, and budget deficits at all levels of government make fraud and abuse the top health law issue for 2011, according to *BNA's Health Law Reporter* advisory board members.

A deluge of regulations to implement new health care industry reforms and a government push to off-set outlays with monies from settlements and other enforcement actions, including the dual threat of individual liability for corporate wrongdoing and increased whistleblower clout, raise many concerns, board members said.

The complex changes wrought by reform and the regulation of the accountable care organizations (ACOs) that are central to its success will require a revamp of antitrust, tax, and fraud and abuse regulations to permit the level of clinical integration and coordination of care ACOs need to be effective without running afoul of current laws, Robert L. Roth, with Hooper, Lundy & Bookman PC in Washington, said.

Antitrust developments came in second in board members' ranking of the Top 10 issues facing health lawyers in 2011. Rounding out the list were financial stresses in the Medicare/Medicaid programs, health plan regulation, protection of health information, the need for better patient care quality and its effect on the provider's bottom line, medical staff issues, taxation, corporate governance, and labor and employment issues. These issues were seen by board members as being affected by health care reform for the foreseeable future.

Critical among compliance challenges are those involving ''medical loss ratios'' (the minimum percentage of premiums that must be paid out for medical care) and the requirements for exempt hospitals to conduct community health needs assessments, attorneys said. But many other issues also loom large.

In the picture are final regulations under the Health Information Technology for Economic and Clinical Health Act (HITECH), which created financial incentives for adopting and utilizing electronic health records (EHR) and penalties for those who do not. The rules are due out soon, after which there will be a very short time line for compliance, W. Reece Hirsch, of Morgan, Lewis & Bockius LLP in San Francisco, said.

Meanwhile, Dawn R. Crumel, with Children's National Medical Center in Washington, sees hospitals' increased use of cloud computing and remote hosting making protecting privacy even more difficult and complex, a danger Elisabeth Belmont of MaineHealth in Portland, Maine, says is exacerbated by social network sites and widespread physician use of smartphones that access the internet.

Medicaid presents other great unknowns. Although Medicaid's actual expansion will not occur until 2014, the health reform law will require a ''total redesign'' of state programs and create intense economic pressure on states at the same time those with corporate practice of medicine laws will find it hard to compete, given new PPACA-driven changes.

Looking further into the future, John D. Blum, of Loyola University Chicago Institute for Health Law, said he believes that expanded access under PPACA and the shortage of primary care physicians will cause telemedicine to become a necessary alternative to traditional care. However, current telemedicine regulations are ''underdeveloped,'' he said, and the Centers for Medicare & Medicaid Services (CMS) will have to address them in a more comprehensive fashion than its incremental and cautious approach of the past.

Although a couple of advisers were more sanguine, almost all questioned whether the government is up to the task of accomplishing all that needs to be done to restructure the nation's massive and complicated health system.

Up to the Task? Roth said that although CMS has tended to be increasingly responsive to provider inquiries over the past couple of years, three recent trends seem to have inhibited its ability to address problems quickly, even relatively minor technical ones.

The first, Roth said, is the loss in recent years of ''significant institutional memory as the result of retirements etc. just as Medicare has become significantly more complex.'' Apparently, CMS's response has been, in part, to decentralize decision making to allow different agency components to develop necessary expertise quickly. However, with the increase in statutory and regulatory complexity, the unfortunate result is that making a decision takes more time because several CMS components must be consulted, making this decentralization the second factor inhibiting nimble problem-solving. The third factor, Roth said, is the general governmental increase in ''outsourcing'' tasks to the private sector, which causes CMS to retain less direct control over, or even knowledge of, decisions and

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Health Law Reporter's Top 10 for 2011

Advisory board members ranked these the most important health law issues for 2011:

1. **Fraud and abuse** threatens individual liability for corporate noncompliance with complex and evolving rules.

2. Increased enforcement and the focus on the effect of ACOs on competition make **antitrust** issues key.

3. Changes and stresses in **Medicare**/**Medicaid** programs have ripple effect throughout health care.

4. Insurers deal with unprecedented changes in **health plan regulation**.

5. **Health information** remains an important provider investment and compliance focus.

6. Emphasis on **quality** pervades health care delivery, payment systems.

7. The future of the **medical staff** becomes murky in an age of physician employment and ACOs.

8. **Taxation** issues under new Section 501(r) challenge IRS and exempt hospitals.

9. Compliance pressures on corporate executives and board members up the ante on proper **corporate governance** programs.

10. **Labor and employment** issues remain significant challenges for providers.

detailed operational systems that have been delegated to Medicare contractors. As a result, decision making is fragmented among the CMS central office, regional offices, contractors and their CMS contracting offices. ''Problem-solving among a group this size is inherently difficult but the challenge becomes greater when you factor in potentially different priorities/concerns of the various players,'' Roth said.

Douglas Ross, of Davis Wright Tremaine LLP in Seattle, looked beyond CMS. ''Congress simply cannot pass extraordinarily complex laws that give vast responsibilities to federal agencies that are beyond their capabilities to handle, and then think it is going to work,'' he said. Ross cited a speech by Federal Trade Commissioner William Kovacic at a meeting in Seattle in December in which ''he essentially said that we do not have the institutions that are capable of administering something as complex as the health care reform law.''

'Unrealistic Expectations' of Congress. Howard A. Burde, of Howard Burde Health Law LLC in Wayne, Pa., concurred, saying that ''PPACA and HITECH have created a regulatory mandate overload that is not the fault of the regulators but the unrealistic expectations of Congress in rushing to pass laws without sufficient consideration of the practical aspects of implementation.'' The minimums set for medical loss ratio is a case in point. The Treasury Department's request for comments on how MLR requirements should operate (75 Fed. Reg. 19297, 4/14/10) resulted in a 70-page response, complete with appendices, from the National Association of Insurance Commissioners, revealing a complexity politicians may not have anticipated. How well it will operate remains to be seen.

Several advisers cited divisive politics as the root of the problem. ''As health care becomes a political football and a factor in the next presidential election, anything goes,'' Katherine Benesch, of Duane Morris LLP in Princeton, said. ''Decisions made will not necessarily be rational and health care providers, as consumers of one of the largest parts of the federal budget, will continue to take abuse. Payment reform may have to be initiated by private parties as elected officials do not seem capable of working together to enact the difficult cost containment mechanisms that are necessary.''

Jack A. Rovner, of the Health Law Consultancy in Chicago, questioned specifically if the Republican House ''will strangle the funding required for HHS to implement PPACA'' and if ''Republican-controlled state legislatures and/or executive branches will eschew or stall PPACA provisions left to state implementation.'' More fundamentally, he asked, ''Can the private sector realistically absorb the mountains of implementing regulations issued and to be issued to survive or even thrive in post-PPACA markets?''

''This year will feel more than ever as if we are squeezing a balloon.''

FREDRIC J. ENTIN
POLSINELLI SHUGHART, CHICAGO

Others wondered if PPACA itself will change before the new year is out. Talk of health care reform brought two words to Kirk Nahra's mind: change and confusion. The health care industry has devoted an enormous amount of resources to understanding and preparing to implement PPACA's substantial new set of programs and policies, he said, but even before most of these programs have begun and their effects felt, there is a possibility that some (or all or most) will be revised or eliminated. ''So, we are continuing to impose change and new cost (both in dollars and in compliance obligations) without giving these programs any time to evolve or demonstrate if they are working,'' Nahra, with Wiley Rein LLP in Washington, said.

''While it is clear that the PPACA efforts will not 'solve' the health care crisis, the question over the next few years is whether we are going to improve the system in any meaningful way or whether we will simply add to the problem by imposing new costs and challenges without waiting to see if there are any benefits,'' he said.

Gerald M. Griffith, with Jones Day in Chicago, said he believes that while some attempts may be made ''to at least tweak the legislation,'' most of the activity over the next two years will shift to the regulatory arena. The coming year will bring an ''onslaught of midnight regulations,'' a flood of regulatory activity on health care reform, he said.

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As a result, Fredric J. Entin said, ''This year more than ever will feel as if we are squeezing a balloon; as soon as we understand and adjust to one issue, the solution may cause another to pop out the other side of the balloon, demanding attention to one or more other issues.'' Entin is with Polsinelli Shughart PC in Chicago.

1. Fraud and Abuse. ''Current fraud and abuse laws, passed with fee-for-service and DRG [diagnosis-related group] payments to providers in mind, seek to make illegal practices that would lead to over- or underuse of appropriate medical services,'' Douglas A. Hastings, of Epstein Becker Green PC in Washington, said. Today, with greater understanding of evidence-based measures, ''we can more readily identify proper use, overuse, underuse, and misuse. Thus, the definition of fraud and abuse must evolve along with enforcement priorities.''

CMS and the Department of Health and Human Services Office of Inspector General are working on protecting and supporting financial incentives to drive provider collaboration and bring about the coordinated care PPACA requires, he said. Rules may be coming out in 2011 with waivers under that statute and/or new safe harbors, and it is ''critically important for them to get the balance right between appropriate collaboration on the one hand and kickbacks and improper financial relationships on the other,'' Hastings said.

In any case, liability for health law violations will be even more on the minds of providers and their counsel in 2011, HLR advisers said. In 2009, the Fraud Enforcement and Recovery Act made violations of the Stark law violations of the False Claims Act, Benesch said, allowing the government to collect treble damages ''in many more circumstances than in the past.'' PPACA then provided enforcers with new anti-fraud tools and expanded both the circumstances under which liability may arise and the consequences of such liability. It expanded the FCA and lowered the bar for whistleblower litigation, with the result that, as Howard T. Wall III put it, ''health reform has raised the bar on health care compliance programs.'' Wall is with Capella Healthcare Inc. in Franklin, Tenn.

Meanwhile, Sanford T. Teplitzky with Ober Kaler in Baltimore sees ACOs in particular creating difficulties ahead. ''Few people have a real clue as to what they are, and what they are supposed to accomplish,'' he said. ''The problem is that all of the existing fraud and abuse sanction authorities were developed at a time when the goal was to ensure that health care providers remained in their own 'silos,' '' each billing for its own services. ACOs are ''anti-silos''; they require that all players work together to improve qualify and efficiency and reduce costs. ''But with the fraud and abuse laws substantially constricting the manner in which health care providers can be financially integrated, until we have such guidance and the answers to these questions, many health care providers will be hesitant to think and act creatively when the result may be accusations of violating the Stark law and federal anti-kickback statute,'' he said.

Teplitzky added that relator-initiated cases continue to increase. Additionally, the allegations contained in these FCA cases continue to be more aggressive, he said, with no sign the trend will slacken. Some court cases can be seen as ''attacking previously-thought-to-be-protected employment relationships, as well as the reliance upon third-party independent valuations,'' he said. Furthermore, Teplitzky said, states with their own false claims statutes are becoming more aggressive in investigating and pursuing cases under those statutes, complicating the ability of defendants to achieve global resolutions of allegations.

Entin cited more and better data mining as a key enforcement resource. ''RACS [recovery audit contractors], ZPICs [zone program integrity contractors], and MICs [Medicaid integrity contractors] are harnessing the power of computers to find overpayments or fraud and providers will find the number of requests for records demands for recoupment, and referrals to enforcement agencies on the rise.'' Furthermore, data-mining is used not just by contractors. ''As can be seen by contact letters DOJ sent this fall in its investigation of implantable cardioverter defibrillators whose use allegedly did not meet Medicare coverage requirements, providers will be hit from all angles as a direct result of the power of data mining,'' Entin said.

Belmont and others cited the threat of individual liability as a huge fraud and abuse issue for 2011. ''The recent indictment of a pharmaceutical company's in-house counsel (*United States v. Stevens*, D. Md., No. 10-CR-694, 11/8/10) serves as a strong indication of the government's willingness to use obstruction-based criminal prosecution theories to address the conduct of individuals in responding to government investigations,'' Belmont said. It also shows that prosecutors are not reluctant to target individuals they believe are responsible for corporate misconduct, she added. ''Obstruction risks should be of particular concern to the health care inhouse counsel, whose 'internal clients' are contacted by government investigators with a frequency seemingly unsurpassed in other industry sectors,'' she said.

Richard Raskin, of Sidley Austin LLP in Chicago, said potential liabilities will continue to be at the forefront in 2011 and beyond, but ''the real headline issue is the individual prosecution of pharma and medical device executives.'' Both the Department of Justice and OIG have moved from talking about individual responsibility to aggressive action under the *Park* doctrine (where individual officers are held criminally responsible for the conduct of others) and to direct allegations of individual wrongdoing.

Wall had both good news and bad news for providers. He welcomed an indication that CMS will shift its enforcement focus from ''pay and chase'' to prevention of wrongdoing, meaning that instead of going after providers who make mistakes, HHS enforcement officials will be going after organized fraud schemes and criminal conspiracies. ''It still remains to be seen,'' he added, whether other law enforcement officials, the U.S. attorneys particularly, will follow suit. But Wall also said that in releasing its Stark Self-Disclosure Protocol in September 2010, ''CMS passed on the opportunity to distinguish technical Stark violations based on purely administrative errors (e.g. unsigned agreements and inadvertent nonrenewals of lease terms) from the kind of the violations the statute was meant to address. It thus remains to be seen whether technical violations will be reported under the protocol or whether it will be used only for substantive violations where the case for repayment is clear,'' Wall said. Teplitzky added that the government's failure to provide guidance and some cer-

tainty as to how these situations will be handled has led to ''confusion and concern.'' How CMS will address these situations will be watched closely in the months to come, he said.

Both Mark A. Kadzielski, of Fulbright & Jaworski LLP, in Los Angeles and Nahra expect more aggressive government prosecutions, even as the government is appropriately focusing attention on the importance of compliance programs. Griffith said he expects that ''arrangements historically viewed as normal, necessary business transactions will be targeted'' more frequently. He cited the *Christ Hospital* case (*United States ex rel. Fry v. Health Alliance of Greater Cincinnati*, S.D. Ohio, No. C-1-03-167, *dismissed* 2/2/10; 19 HLR 208, 2/1/10) as an example of the increasing vulnerability of ''apparently innocuous business transactions''—in that case, trying to recruit physicians to fill a call panel which, despite the government's assertion that panel time was something of value, the hospital historically had not been able to fill. ''Simply addressing a community need is no guarantee that the government will agree an arrangement is compliant with the kickback and self-referral laws,'' he said. More recently, the *Bradford Regional* case (*United States ex rel. Singh v. Bradford Regional Medical Center*, W.D. Pa., No. 1:04-cv-00186-MBC, 11/10/10; 19 HLR 1591, 11/18/10) indicates that joint ventures also are a potential target, Griffith added, meaning that providers should expect to be spending more and more time and resources defending transactions that may prove, in hindsight, to have been too aggressive.

Nahra said he also sees the potential for conflict of interest. ''Shifting perspectives on fraud enforcement have created substantial new pressures to generate enormous anti-fraud recoveries, creating significant conflicts of interest in the government, with the need to generate fraud recoveries almost regardless of the basis for these recoveries. This threatens to create a fundamentally unfair approach in the anti-fraud area, where the government's position and leverage—already incredibly strong—are increased significantly while the government's appropriate discretion is challenged by the pressure to generate recoveries.'' What he fears, he said, is that the economic pressure for fraud recoveries at a time of massive new regulations demanding fundamental change may create ''an inappropriate pressure to move forward with enforcement even before the kinks have been worked out in the system.''

Others agreed. Ross said many see fraud and abuse enforcement as ''the key to balancing the budget,'' while Benesch said that U.S. attorneys, state attorneys general, and insurance fraud prosecutors see ''providers as a source of financing to cover the cost of state and federal governmental operations.'' Ironically, she added, this raises the cost of health care delivery as providers are forced to spend increasing amounts on administrative personnel needed to respond to governmental demands.

2. Antitrust. Antitrust moves close to the top of the list for 2011 because of an increased emphasis on government enforcement, affecting both providers and payers; because an increase in new and follow-on private enforcement actions also is likely; and because health care reform and economic conditions appear poised to push a higher rate of provider consolidations and joint ventures, board members said.

Antitrust law issues also appear central to the post-PPACA health care delivery and health law compliance landscapes because of the ''flurry of interest in ACOs'' and conflicting predictions regarding their effect on health care competition, they said. It is unclear, however, whether government guidance actually will clarify which types of provider collaborations will pass a regulatory ''litmus test,'' several members added.

Eric A. Tuckman, of Advisory Health Management Group in Manhattan Beach, Calif., said he expects 2011 to bring a continuation of the government's new heightened antitrust enforcement approach to health care mergers and acquisitions. ''Under the Obama administration, there has been a clear and fundamental change in the regulatory review process at the FTC that has resulted in increased antitrust scrutiny,'' Tuckman said.

''In 2001 we are likely to see the continued use of nontraditional analytical methods to determine if there are anticompetitive effects, including an emphasis on quantitative evaluations and a continued move away from traditional market and product definitions,'' Tuckman said. ''This increased regulatory review will focus both on whole hospital/system expansions/integrations and mergers and acquisitions involving relatively smaller ancillary service providers, such as labs, surgery centers, and imaging facilities,'' he said.

Toby G. Singer, with Jones Day in Washington, said she anticipates that ''increased government enforcement efforts—especially on the DOJ side—will continue.'' She pointed to DOJ's lawsuit against Blue Cross Blue Shield of Michigan (BCBSM) over the use of most-favored-nation clauses in health plan/provider contracts, which has been followed by a number of private actions, saying these lawsuits ''may break new ground.'' ACOs ''are likely to be the focus of health care reform-related antitrust cases and hospital, physician, and health plan consolidation will all be looked at carefully by the enforcers at both the federal and state level,'' she added.

Antitrust enforcement is ''a real wild card for 2010.''

KIRK NAHRA
WILEY REIN LLP, WASHINGTON

J. Mark Waxman, with Foley & Lardner in Boston, agreed, citing ''the increasing level of attention at every level, lobbying activity, judicial activity, FTC activity, that indicate that antitrust is making a comeback.'' Greater attention is being placed on the market power of competitors to shape health care delivery, and recent cases involving BCBSM and hospitals in Pennsylvania suggest ''we can expect to see far more antitrust fireworks in the next several years,'' Waxman said.

Nahra called antitrust enforcement ''a real wild card for 2010.'' He called the government's action against BCBSM ''a shot across the bow on health insurer practices'' that appears to be the first in an initiative of sorts that threatens core contracting activities of health insurers.

Rovner said he, too, expects an increased antitrust focus on health insurers in 2011, particularly as PPACA health insurance market reforms are likely to spur

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health plan acquisitions and consolidations. ''DOJ's case against BCBSM for alleged anticompetitive provider contracting activities also bears watching,'' he said.

Benesch predicted more private antitrust litigation, saying that ''as services and provider groups consolidate, there will be more antitrust challenges from those who believe they have been left out of the more concentrated systems.''

According to Entin, antitrust will be a hot area in health care. While health care antitrust enforcement has been identified as a priority for both FTC and DOJ, these agencies have acknowledged the validity of provider concerns over liability as new provider relationships are contemplated to form ACOs in response to health care reform, he said.

''Organizations already engaged in clinical integration may have a head start on others but I would expect that the agencies will maintain a healthy amount of skepticism and be on the lookout for sham organizations that neither share financial risk nor truly engage in clinical integration,'' he said.

Stephanie W. Kanwit, with Manatt Phelps Phillips LLP in Washington, agreed that ''everyone is anxious to see the upcoming regulations on ACOs, now scheduled for release in January, which will have implications not just for the public programs like Medicare but also the commercial insurance market.'' Those regulations are expected to address the potential problems associated with a ''headlong rush to integration by providers who were previously competitors that could lead to undue market power and undermine the very promise of ACOs,'' Kanwit said.

The federal antitrust agencies have a tough job of '' 'threading the needle' in defining how far an organization must clinically integrate to allow for accountability,'' she added. ''The goal is to foster flexibility that truly leads to innovative care and payment models without at the same time giving the green light to undue market concentration or other antitrust problems,'' she said

T.J. Sullivan, with Drinker Biddle & Reath LLP, Washington, cited the same conflicting agency initiatives—helping to spur health care delivery innovation and working to enforce antitrust laws vigorously—as reasons health care antitrust will remain an important compliance focus for health lawyers. ''On the one hand, with the FTC looking at already completed mergers, people are once again paying attention to the rules. On the other, the FTC will have to reach some accommodations with respect to existing regulation in order to encourage cooperation in the development of ACOs,'' Sullivan said.

Wall cited the ongoing FTC and DOJ discussions on regulatory barriers to the development of ACOs as illustrating the importance that the antitrust laws will play in defining the future of health care delivery. ''The big question is whether the FTC and DOJ will be willing to modify their notions about clinical and financial integration to allow the innovations that are sure to arise out of the accountable care experiment,'' Wall said.

''Beyond ACOs the other likely test of the antitrust laws will be the surge in consolidations,'' Wall predicted. ''Many markets simply cannot sustain the number of independent competing providers that exist today, so antitrust law enforcers will have to recognize that the rapidly changing health care economic environment requires a loosening of traditional definitions that stand in the way of desperately needed consolidation,'' Wall added.

Nahra agreed, calling antitrust policy ''a key consideration in achieving some of the potential benefits of some of the important health care reform ideas, such as ACOs. Therefore, how antitrust policy evolves over the next year or two will be an important overall component in the health care industry.''

Hastings said antitrust was high on his Top 10 list primarily because of the ''furious debate over the impact of PPACA's incentives and requirements for care coordination among providers on provider market power and provider pricing.''

Ross noted the tension between those parts of the government that are pushing health care reform—including CMS—and the antitrust enforcement agencies, in particular, the FTC. ''The federal enforcement agencies are aggressively reviewing health care mergers and acquisitions and are likely to be suspicious of the formation of ACOs in any community where the ACO will account for a substantial portion of the available providers—which will be every community outside of major metropolitan areas,'' Ross said.

''Odds are high that the guidance the FTC and DOJ are working on will be much ado about nothing: the agencies may indicate they will try to expedite requests for antitrust reviews—something they have said before—and may issue a safe harbor or two,'' Ross said. However, safe harbors that are unlikely to depart substantially from the guidance given to provider networks in the 1996 Statements of Antitrust Enforcement Policy in Health Care will not please the industry and may not please CMS he added.

Rovner identified the same themes—the push for ACOs, ''which are all the rage,'' and stepped up health care antitrust enforcement—as issues that will keep antitrust in the foreground of health lawyers in 2011. ''The question is whether the ACO concept can or will live up to the hype and bring financial and quality accountability to provider delivery of health care for defined populations, or whether ACOs will become a pretext for providers to increase market power to control price and extract even higher prices from health plans, employers and patients,'' Rovner said.

Blum said he expects an increase in both government and private enforcement action as major provider realignments are sparked by the development of ACOs and the prospects of bundled payments. ''In some instances, this market realignment may spark the need for regulators to grant waivers from antitrust laws if this area of law becomes a serious impediment to system reorganization,'' Blum added.

Raskin said the great debate between those who see consolidation as a blessing and those who see it as a curse is taking shape in health care antitrust.

''On the one hand, market and regulatory developments, including PPACA, appear to encourage and reward consolidation among providers. The message is that a fragmented health care system cannot be expected to deliver consistent quality and value and that capital investment is needed to build infrastructure and connect caregivers electronically,'' Raskin said.

''Yet consolidation also presents the potential for creating market power, both on the provider side and the payer side,'' Raskin continued. ''How are we to distinguish between consolidation that improves care and

consolidation that harms competition? Are the objectives of health policy and antitrust in good alignment or are they out of whack? How will HHS, FTC, and DOJ—to say nothing of plaintiffs' lawyers and the courts—balance the competing objectives of these laws?''

''Upcoming agency guidance on ACOs will provide one venue to address these questions. Just as important, however, will be reading the tea leaves at the enforcement agencies to determine their approach in dealing with joint ventures and mergers that pose the potential both for market power and for real, measurable improvements in quality and efficiency,'' he said.

3. Medicare/Medicaid. Changes to the Medicare and Medicaid programs called for under PPACA, and other adjustments that many predicted are yet to come, will ''drive a new generation'' of health law, board members said. Meanwhile, how states, whose budgets already are strained, respond to the expansion of Medicaid under health care reform will be an especially important area to watch, they said.

Several also pointed to the potential ripple effects of government program changes as reimbursement shortfalls likely will be shifted to providers and commercial payers putting more pressure on plan and provider contracting at a time when insurers are being pushed to keep coverage affordable.

According to Hastings, Medicare and Medicaid remain at or near the top of the Top 10 because federal payments under these two programs have a huge budgetary impact and are a principal driver of behavior in the health care system. ''The need to coordinate policies and approaches in the public and private sectors has never been more important,'' he said.

''Implementation of the PPACA as it relates to Medicare and Medicaid will drive legal issues and interpretations in high volume for years to come through new regulation, amendments to the law, government guidance, government enforcement, and private sector responses,'' Hastings added.

Benesch agreed, noting that Medicare ''is at the forefront of the health care reform discussion due to the ever-escalating cost of care, the dwindling trust fund reserves, and the increasing age of the population. While a change in the payment paradigm seems to be one of the only ways to significantly effect this issue, this has not yet happened,'' she noted.

''Many of the demonstration projects CMS will be funding under the new reform laws will address the issues of payment reform. In the meantime, Medicare reimbursement rates will continue to be at issue and key to the success or failure of the ability of providers to continue to deliver care to Medicare recipients,'' Benesch said.

''In addition, new payment limitations, such as Medicare's refusal to pay for patients who are readmitted to the hospital, will increase the financial stress in the hospital reimbursement system,'' she added.

Waxman called Medicare ''a fluid program with so much going on in payment changes that it is a challenge just to keep up with all the activity from an operational standpoint.''

Rovner said that Medicare will continue to generate legislative attention, noting that, while Congress ''acquiesced to an eleventh-hour save to Medicare physician reimbursement rates, it still faces management of—and physicians still face the uncertainty of—the Medicare sustainable growth rate (SGR) formula.''

''Will Congress in 2011 finally tackle revamping and/or replacing the SGR formula? Can Congress do so with deepening federal deficits and a Republican-controlled House sworn to 'fix' that problem? Only time will tell,'' Rovner said.

Vicki Yates Brown, with Frost Brown Todd LLC, Louisville, Ky., pointed to changes she expects to see in the Medicare Advantage (MA) and Part D programs, noting that ''large reductions in payments for MA contracts set to begin in 2011 will cause a phase out of the Medicare Advantage program while the phase out of the Part D coverage gap will result in significant changes in that program.''

Board members zeroed in on the fact that, while PPACA relies heavily on the states to implement change, state budgetary woes may make it difficult for them, even with enhanced federal support, to fulfill their responsibilities.

With the passage of PPACA, and the fear that the individual mandate could push millions of new beneficiaries into state health care programs, board members agreed that Medicaid will be a big issue in the coming months.

Blum observed that, while the actual Medicaid expansion may not occur until 2014, states must prepare now for how they are going to deal with what may need to be a total redesign of their programs. ''The success of PPACA rests on the cooperation of the states and no area will be more critical than Medicaid. Even with an infusion of federal monies to states, however, the economic pressures on state governments make this expansion highly problematic.''

Board members said state budgetary woes may make it difficult for states, even with enhanced federal support, to fulfill their responsibilities under PPACA.

Benesch agreed that the Medicaid program ''is at a pivotal point, as the health care reform laws are expected to increase the number of individuals covered by Medicaid by 32 million people, without a corresponding increase in payment to providers for delivery of services to Medicaid beneficiaries. With responsibility for 50 percent of the funding to this increased number of Medicaid beneficiaries, state governments will be under extreme pressure to find ways to finance these services,'' she added.

Waxman called Medicaid ''the experimental cauldron that gives different states the opportunity to try different approaches, with challenges all around.'' He said that access will remain an issue and that tight state budgets and the difficult financial environment will lead many to question whether Medicaid reform that works even is possible.

Roth said he thinks Medicaid will be a top issue ''because the federal government and the states have spent the past couple of years building a vast Medicaid enforcement infrastructure.'' He also predicted health

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lawyers will stay busy defending providers from state Medicaid budgetary cuts.

Sullivan said the ''big issue with Medicaid is how states react in absorbing the huge influx of new beneficiaries, how they manage rates, and whether, as has been rumored, certain states consider pulling out of the program and substituting a more limited solely state-financed program.''

Crumel also pointed to this dynamic, saying that, as more people may become eligible for Medicaid through PPACA, states may begin to reduce the level of reimbursement for services. ''Hospitals will continue to require compensation for disproportionate charity care until access to the health care system effectively is redesigned and the entry point to the health system no longer is the emergency room,'' she said.

Ross questioned how states will be able to fund Medicaid as they continue to suffer through budget crises. ''The decrease in these funding sources will force providers to shift more of their costs to commercial payers. The question then becomes how will commercial payers deal with this, especially as politicians and consumer groups insist that insurers do more with less,'' he said.

Rovner agreed, predicting that, ''as more people without employer-based health coverage will become Medicaid eligible, state and federal resources, already stressed by shrinking tax revenues from shrinking business revenues and personal incomes, will become more burdened and force more reductions in what states can or are willing to pay providers for Medicaid services.''

If some states follow through on their threats to pull out of Medicaid, PPACA could have the perverse impact of actually shrinking the very safety-net program it sought to expand, Rovner said. ''Some states, on the other hand, may opt to run their Medicaid programs through their PPACA health insurance exchanges, allowing Medicaid beneficiaries to use premium subsidies to select private coverage,'' he added.

4. Health Plan Regulation. Board members stressed the fact that PPACA, perhaps more than anything else, was ''health insurance reform,'' and that few areas would be as affected by health care system changes. Health insurers will, for the first time, be the subject of extensive federal regulations and are likely to have to deal with a ''shifting sands'' environment as the new Congress appears poised to make modifications to the health reform landscape, they said.

A changed relationship with providers also is likely because of contracting tensions driven by reduced government program reimbursement to providers and extensive pressure on health insurers to comply with medical loss ratios and minimize premium increases. Positive change in these relationships could result if insurers and providers can find ways to align around quality improvement and integrated delivery initiatives, they added.

Nahra noted that health plans ''are at the epicenter of the ongoing debate about health care reform'' and that, while there are challenges facing everyone in the health care industry, the health plan community is facing a full scale attack on its entire way of doing business, a monumental set of new challenges created by PPACA, and the very real possibility that—despite the millions and millions of dollars spent on getting ready for these changes—the system will change yet again because of the political shifts in Washington.

''In addition, through the 'back door' of the medical loss ratio rules, the health plan industry is facing a new set of aggressive oversight policies that delve into critical details of every aspect of their operations. With new regulation at both the state and federal level, ongoing and perhaps unprecedented change and a less than positive reputation in the public, the health plan industry is facing challenge like none before,'' Nahra said.

Kanwit said that, from a regulatory perspective, health insurers are watching as HHS moves to define the scope of the ''essential benefits'' package—a federal standard health plans will be required to meet—in a way that maximizes value while ensuring affordability. They also are waiting to see what HHS and the states come up with in the health insurance exchange arena. ''Both of these tasks need to take into account actuarial principles so that rates are reasonable in relation to benefits and the population covered; otherwise, there will be disruptions of coverage for consumers and fewer choices as insurers are forced to exit the market,'' she said.

Kanwit suggested that ''one positive template to consider as reform is implemented is the success of Medicare Part D in keeping drug prices reasonable for beneficiaries and coming in 'under budget.' '' That program is based on the concept that multiple competitors fielding multiple products can help consumers find the right product for their particular situation, she noted.

Kanwit also cited the ACO phenomenon, saying there are ''huge implications for the commercial insurance market'' apart from the economic, quality, and competition issues ACO discussions generally dwell on. ''The caveat for these organizations is that, if they are to be successful, they need to build on the mistakes of the provider-sponsored organizations in the 1990s, which often floundered as a result of taking on risk,'' Kanwit said.

''That problem of risk is a primary reason that it's simplistic to talk of ACOs as involving just physicians and hospitals working on innovative care and payment models; the fact is that health plans are integral to any such massive delivery system transformation, with their historical essence being management of risk,'' Kanwit added. ''It will be a bumpy road as we proceed from a heavily fee-for-service system in Medicare to the nirvana of true value-based care throughout the system.''

Hastings said there is no question that PPACA's ''massive set of requirements relating to health care access, paying for it and regulating health care insurance constitute the most politically divisive components of the new law.'' Although these provisions ''surely will be subject to ongoing debate and amendment, employers, health plans, providers, and consumers all are affected to some degree today, while also needing to prepare for bigger changes to come in the years ahead even in the face of significant uncertainty,'' Hastings said.

''That requires very careful analysis and forward thinking by the legal advisers in both the public and private sectors,'' Hastings continued. ''Of all of the new requirements, I would single out the medical loss ratio regulations as perhaps having the greatest long term impact.''

Sullivan said that medical loss ratio requirements and the ban on enrollment cancellations is only the beginning. ''The insurance industry has so far avoided the ending of different regulations in different states, but the federal government is going to level the playing

field somewhat with an overlay of critical regulation,'' he said. ''Insurers will go back to competing by better managing risk and care, rather than avoiding risk.''

Rovner agreed that PPACA will continue to put intense pressure on health plans in 2011 and beyond to revamp their operations, their expense structures, their data collection and reporting capabilities, and, perhaps, even their business models.

''While PPACA forced health plans to make many changes in health benefit designs in 2010—such as no preexisting condition exclusions, extending dependent coverage to age 26, covering preventive care without cost-sharing, elimination of lifetime limits—2011 will force health plans to confront and intensify planning for managing medical loss ratio thresholds and rebates, 'unreasonable' premium increase oversight, and selling health insurance coverage through state health benefit and small business health options exchanges,'' Rovner said.

''Health plans will also need to adjust to deal with forthcoming HHS oversight of 'unreasonable' premium rate increases. 2011 will also mark the year when most states begin actively planning to establish their PPACA-qualified insurance exchanges,'' Rovner said.

''We can expect legislative and executive activity as each state and the broad range of stakeholders within each state try, hopefully with success, to work together to fashion a viable exchange framework to provide an effective marketplace for individual and small group health insurance coverage by 2014,'' he said. ''HHS cannot be ignored in the exchange development process, particularly in the current political environment.''

''Health plans also have reason to watch closely in 2011 the court battles over the constitutionality of PPACA's individual mandate. For health plans, the individual mandate is a critical component in controlling adverse selection and making the PPACA 2014 insurance market reforms work,'' Rovner said.

Rovner also predicted that, ''With medical costs being the primary driver of health plan premiums and with health plans under intense public, political, and PPACA pressure to check premium increases, health plans may be expected to vigorously resist provider demands for increased reimbursement and, perhaps finally explore in earnest alternatives to fee-for-service reimbursement built on Medicare rates.''

5. Health Information. Two health information-related issues likely will provide work for attorneys in 2011, according to HLR board members: the adoption of health information technologies, such as electronic health records (EHRs) that support the use of health information exchanges (HIEs), and the new security and privacy regulations issued pursuant to the Health Insurance Portability and Accountability Act (HIPAA) and the HITECH Act.

''The information revolution is finally coming to health care,'' according to Raskin. He said this ''means huge investments, enormous opportunities for quality improvement and innovation, new legal issues, and a new spin on the old issues.''

Nahra said health information technology likely is ''one of the few possibilities for a 'win-win' in the health care reform debate.'' He said this ''technology can significantly improve overall care, while decreasing costs at the same time.''

Brown ranked health information as her third most important issue for 2011. She said the ''expansion and use of health information technology to support health care reforms will continue to be encouraged and driven by state and federal government,'' leading to issues for providers and suppliers.

Wall called 2010 ''a huge year for health IT,'' but predicted ''2011 will be even bigger.'' He cited the push to adopt EHRs as ''important both economically and politically.'' It will be interesting to see ''whether the newly elected GOP majority in the House . . . will follow their . . . promise to cut off all unspent stimulus money, which includes most of the $20 billion in HITECH Act money'' that hospitals are counting on to fund technology updates.

The future of the EHR incentive program caught Belmont's attention as well. She noted that the incentives ''start in 2011, but become penalties by 2015 through reduced reimbursements for those who do not achieve meaningful use.'' The meaningful use standards, adopted by CMS earlier this year, ''begin to define 'a common language to ensure accurate and secure health information exchange across different EHR systems,' '' she said.

Belmont said that in 2011, ''eligible hospitals and professionals will be focused on meeting the criteria to receive incentive payments for achieving meaningful use of certified EHR technology and avoiding penalties for failing to achieve meaningful use that being in 2015.''

2010 was "a huge year for health IT,"

but "2011 will be even bigger."

HOWARD T. WALL
CAPELLA HEALTHCARE INC., FRANKLIN, TENN.

''In 2011, there also will be an increased focus on EHR vendor contracting issues as eligible providers select an EHR vendor, ensure that the EHR product by itself or in combination with other EHR modules will achieve, or can be modified by the vendor to achieve, certification,'' she added. ''Providers will need to carefully review contractual commitments to achieve interoperability of modules, certification and meaningful use. Vendors will need to provide assurances that products will be certified and that they will enable meaningful use.''

Wall said ''there may be additional tweaks and delays'' with respect to the meaningful use definitions, but that ''it is highly unlikely that major changes will occur.''

Entin said, however, that ''yet another revision of the rules may be required'' because ''the criteria for meaningful use may still be too difficult, with the result that EHR adoption has not been stimulated as expected by the administration.''

Entin noted that providers ''have been frustrated by efforts to meet eligibility requirements for EHR incentive payments from CMS and are looking for alternative financing sources.'' But ''alternative financing will raise privacy, kickback and conflicts of interest issues for those who are finding the government programs too difficult to participate in,'' he cautioned.

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Moving on to HIEs, Nahra added that the goals of using health information technology to improve care and reduce costs ''will be achieved only if the new electronic exchange systems are built wisely. . . .To date, there is a real concern that the costs of the system are substantially higher than anticipated, progress is much slower, and the emerging regulatory framework threatens to eliminate (or at least reduce dramatically) the possibilities of these benefits actually coming to fruition.''

Crumel agreed that the ''potential benefits of efficiency and continuity of care with decreased costs through health information exchange continue to be one of the greatest means to impact the delivery of health care.''

Rovner added that health information technology ''remains critical to effect reformation of health care delivery.'' However, he said: ''Current economic conditions, continued provider—particularly physician—reluctance to invest in HIT, continuing questions about the usefulness and effectiveness of available HIT solutions for interoperable electronic health records, and confused and confusing regulatory schemes for implementing HITECH 'meaningful use,' EHR certification, etc. seem to have sucked steam from the promise and progress for HIT adoption and implementation.''

Brown said the ''expanded use of health information technology'' will lead to an ''increase in compliance issues created by the expansion of [entities] directly regulated by HIPAA and HITECH, as well as increased duties pursuant to the regulations being promulgated under these statutes.''

Driven by these new regulations, privacy and security issues will receive a great deal of attention in 2011, several board members said. Raskin, for example, said he believes ''HIPAA and HITECH will continue to be an important area for regulatory counseling; increasingly, they will also become predicates for enforcement activity and litigation.''

Singer and Rovner agreed. Rovner warned that ''industry needs to brace itself for another round of implementation pressures to come into compliance with new or tightened privacy and security requirements, new business associate contracting mandates and more.''

Nahra noted that the ''traditional HIPAA framework is evolving, although this evolution so far has been slow and incremental rather than dramatic.'' Nahra said that ''while there is no evidence to support the idea that the HIPAA enforcement approach will be significantly different, the government has the tools available to it to engage in substantial enforcement of these rules.''

''Companies facing HIPAA regulation—particularly business associates who have not previously been subject to regulation—need to understand that the risks in this area are substantial and that it is critical to engage in aggressive overall compliance activities to meet these challenges.''

The increased use of health information technology will lead to ''more privacy issues,'' according to Kadzielski.

Belmont warned that attorneys need to be ready to defend clients on HIPAA and HITECH violations resulting from inadvertent disclosure of personal health information via technologies such as iPhones, iPads, and Blackberries, as well as through cloud computing and social media, such as Twitter and Facebook. ''Friending'' patients, ''tagging'' patients, and blogging about (or by) patients all present potential danger zones, she said.

Belmont also noted that providers face potentially increased liability for data breaches. In addition to federal rules, 46 states, the District of Columbia, and the territories of Puerto Rico and the Virgin Islands have laws on the books requiring notification of individuals in the event of security breaches involving their personal information, she said, and states have not been shy about enforcing these laws. In October, for example, Indiana's attorney general filed a lawsuit against WellPoint based on the company's failure to timely disclose a data breach.

Hirsch noted that the HITECH final rule is expected to be released early in 2011. ''Barring significant modifications in the final rule,'' he said, ''many HIPAA business associates and their subcontractors are going to need to conduct security risk assessments and implement HIPAA security rule compliance programs to meet new legal obligations.''

Hirsch said ''there has been a great deal of speculation regarding why HHS withdrew the final HITECH security breach notification rule. Many think that HHS is reconsidering the 'risk of harm' threshold for breach notification that was introduced in the interim final rule,'' he said. The coming year should bring an answer to that question, he said.

Finally, Hirsch said, ''it will be interesting to see how state attorneys general exercise their new authority to bring HIPAA enforcement actions that was created by the HITECH Act. A state AG may be more aggressive than HHS has been both in finding HIPAA violations and in pursuing enforcement,'' he said, citing an action against Health Net brought by the Connecticut attorney general in 2010.

6. Quality of Care. Several HLR board members placed quality of care at the top of their Top 10 lists, with Entin saying, ''If I had to select one topic that has an impact on all the others, it would be quality.''

Hastings called quality ''the prism through which all of the issues in the Top 10 list should be viewed. The core question,'' he said, ''always should be: What solutions to this issue are available that will enhance patient outcomes, patient satisfaction and improve cost efficiency?'' All policy positions and proposed legal solutions should be judged by whether they are likely to ''improve care, improve health, and reduce cost,'' he said.

Entin added that ''PPACA mandates certain payment reforms targeting quality that will drive delivery system changes.'' This ''emphasis on quality will be the underlying theme for long-term delivery system changes. Initiatives to improve quality will require new ways to align incentives between hospitals, physicians, and commercial and government payers,'' he said.

Yet, according to Kanwit, quality has ''been an elusive goal for the health care system, plagued as it is with huge disparities and geographical variations in care, medical care that is not based on evidence, and high costs.''

She said PPACA ''bravely addresses some of those failings'' by promoting the adoption of health information technologies and by changing Medicare reimbursement models to those that ''measure and reward quality.''

Kadzielski agreed that ''despite everyone's best efforts, quality remains as elusive as ever.'' He said, ''One wonders about the real motives behind HHS publishing in November 2010 an OIG report claiming that, in one month in October 2008, 25 percent of all hospitalized Medicare patients experienced a harmful or adverse event. That snapshot study certainly augurs for drastic performance improvement, but such 'scare tactics' may also encourage more malpractice claims, and therefore the practice of more costly defensive medicine. How that will improve quality is uncertain.''

Roth noted that the states, in addition to Medicare, are getting involved with regulatory requirements aimed at addressing quality issues, such as tying payment to outcomes. He sees the trend continuing in 2011.

''The reporting of serious adverse events and the publication by many state health departments such as Indiana and Minnesota of 'best practices' to avoid such events has helped all providers understand that they are not alone in the fight for higher quality,'' Kadzielski added. ''Yet punitive fines against hospitals for these events such as those levied by California's health department—over $5 million to date—are counterproductive in encouraging better care.'' He said ''it is also uncertain whether cash-strapped state health departments in 2011 will adopt the California model of blame and punishment, or whether they will join those states that help hospitals develop a culture of safety.''

Ross warned that ''pressure to improve outcomes and pressure to reduce cost lead in opposite directions.''

''Sure, on occasion quality improvements are tied to cost reduction (e.g., eliminating unnecessary hospital days saves money and lives), [but] it's just not always the case that the health care system can do more with less,'' he said. ''Sometimes when you pay less, you get less.''

Unlike some of the other commenters, Rovner said he believes ''PPACA's principal thrust—to reform health insurance markets to improve access to health care—does little to address health care cost and quality problems.'' He said the ''cost and quality problems vexing the health care delivery system rest with providers and the fee-for-service model.'' PPACA's proposed delivery models ''won't solve these problems,'' he said. ''[O]nly reformation of how providers deliver and are paid for health care will.''

Wall disagreed, saying that ''PPACA contains dozens of important provisions aimed at quality improvements.'' He pointed to provisions that extend quality reporting requirements, impose financial penalties for readmissions and hospital-acquired infections, call for quality measurement development, and create an interagency work group for health care quality as examples.

Wall also said the HHS ''OIG work plan for 2011 again lists quality initiatives as a focal point of enforcement activity.'' And, he said, the ''Joint Commission's pronouncement in the fall of 2009 calling for hospitals to strive for a zero error rate, coupled with the Institute for Healthcare Improvements 5 Million Lives Campaign, are further examples of major initiatives to take health care quality to new levels.''

Saying the patient ''is really number 1,'' Waxman said there is a goal ''to improve patient satisfaction and experience,'' and to take better care of the patient. ''This includes better quality, in a safer environment, with fewer errors, in a more integrated fashion, and with better overall experience at a lower cost.''

''The patient is slowly, but hopefully steadily, moving forward to the center of the care pyramid,'' Waxman said.

7. Medical Staff Issues. ''What is the future of the independent medical staff?''

The question was posed by Wall, but many board members seem to be wondering the same thing, given trends toward clinical integration and employed physicians.

The Joint Commission's newly adopted MS 01.01.01 ''is a clear endorsement of an independent, autonomous medical staff [but] how does the independent medical staff structure function in the context of an ACO?'' Wall asked.

Belmont echoed Wall, asking ''how will the independent medical staff function in the new ACO health care environment?'' She noted the MS 01.01.01 was adopted prior to the contemplation of ACOs as part of health reform.

But Kadzielski said that the '' 'traditional' medical staff will have a lot to say about the rush to ACOs. They will not disappear by a long shot. Ironically, many medical staffs have been cooperating in developing performance indicators and in actually improving performance. To have the results of their hard work being used by ACOs to claim 'shared savings' would certainly be a major point of friction.''

Kadzielski added that he expects to see more conflicts from physician ''disenfranchisement in the realignment rush.''

Blum predicted that ''physician contractual arrangements will have far greater significance than medical staff bylaws in determining the ways in which physicians and hospitals relate to one another.'' And Benesch agreed that ''increased employment of physicians by hospitals and systems will reduce the influence of the autonomous hospital medical staff.''

''A growing number of physicians will abandon the private practice of medicine in favor of becoming hospital employees'' in 2011.

GERALD M. GRIFFITH,
JONES DAY, CHICAGO

Nearly all board members who commented on medical staff issues said legal questions are sure to arise out of clinical integration of hospitals and physicians.

Waxman said it is ''back to the future'' in the area of hospital-physician relationships. Numerous ways are being ''re-explored'' to integrate hospitals and physicians to make care delivery ''more efficient, provide higher quality and better safety, and maintain or lower costs,'' he said. ''But the magic bullet has yet to be found, particularly with those physicians who do not seek hospital employment.''

Tuckman said he foresees ''litigation and disputes clarifying ownership of both the assets acquired and the related revenue streams'' arising out of the failure of structures and relationships created during the past year's ''dramatic increase in hospital/physician integration alignment activities.''

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Tuckman added that ''the increased prevalence of physician employment relationships by both hospitals and medical groups will undoubtedly result in disputes involving noncompete provisions and, quite possibly, a legal redefinition of the entities that are party to the traditional physician-patient relationship.''

''Accelerating acquisition and employment of physicians by hospitals,'' driven by ''ACOs, reductions in physician reimbursement, and social factors (a desire by younger doctors to be employed and avoid the risks—and hassles—of private practice),'' will become issues in the coming year, according to Ross.

Griffith agreed that ''a growing number of physicians will abandon the private practice of medicine in favor of becoming hospital employees'' in 2011. Regulatory bans ''on physician ownership of new or expanded specialty hospitals will exacerbate this trend in some markets,'' he said. But it also could lead to the repeal or creation of broad exceptions ''to the anachronistic corporate practice of medicine laws still in effect in some states, in order to allow for simpler and more cost-effective employment models,'' Griffith said.

''It is not much of a reach'' to predict that legal issues will grow out of the ''fierce competition for physicians and hospitals or other organizations that are fighting to aggregate the necessary resources in the provider community'' to ''achieve the alignment of physicians and hospitals [necessary] to improve quality and position each for enhanced payment incentives,'' Entin said.

''A hospital that envisions itself as the hub of an ACO will need to inventory and bind itself to the minimum number of primary care physicians and specialists in the community to be able to deliver bundled care,'' he said.

Once aggregation issues are resolved, however, questions are likely to arise regarding delivery of care within the aggregated entity. For example, Wall said, an American Medical Association guidance on ACOs ''contains some language that hints at the conflicts that are sure to come.'' In particular, he said, the ''AMA document states clearly that patient care decisions need to be made by physicians. The real question, he said, is: At what point will a mandate follow to practice guidelines, clinical pathways, and other evidence-based methods, referred to as 'cookie cutter medicine,' that will be viewed as a restriction on the independent medical judgment of the physician?''

8. Taxation. Taxation issues will remain prominent considerations for health lawyers in 2011 as the Internal Revenue Service and practitioners sort out requirements codified in the new I.R.C. § 501(r), board members said. IRS will be busy contemplating the ''whats'' and ''ifs'' of any guidance it decides to provide concerning implementation of these provisions while practitioners scramble to move forward as best they can, they added. Meanwhile, Form 990 and Schedule H completion obligations will continue to challenge exempt hospitals at the same time they are under increased pressure from cash-strapped states and communities to defend their property tax exemptions, they said.

Sullivan said the tax issues facing the hospital sector continue to be numerous, complex, and ever-evolving. For example, although Congress has spoken about what it expects from exempt hospitals in return for exemption under Section 501(c)(3), IRS and health care tax attorneys are scrambling to fill a series of legislative ''holes,'' with the former considering what guidance to issue and the latter trying to figure out how to begin to comply based on the information available.

''At the federal level, we now have the clearest sense of what the government expects in return for exemption, and what behaviors the government does not want to see. The IRS has promised us guidance, including a new Schedule H, and this is good, as hospitals need guidance to understand their new duties,'' Sullivan said. ''Minor disagreements as to what PPACA requires in the area of pricing have already flared, so sooner is better for guidance, even if informal,'' he added.

Sullivan suggested that exempt hospitals should be proactive concerning one Section 501(r) requirement—the community health needs assessment (CHNA)—obtaining board buy-in now to the CHNA process they will have to implement shortly and board acceptance of the need for the planning initiative and resource allocation that will result once needs are identified.

Sullivan also cited challenges to exempt hospitals' state property tax exemptions as an issue that will continue to face these organizations due to the economic pressures on local governments. ''Payments in lieu of taxes—or PILOTS—or the threat of property tax exemption challenges will be the rule of the day in many communities,'' he predicted.

Griffith cited Section 501(r) compliance, IRS enforcement, and tax implications of ACOs as three areas that will command a significant amount of hospital tax counsel attention in 2011. He called the CHNA requirement ''a ticking time bomb that could significantly disrupt the status quo of tax-exemptions for nonprofit hospitals.''

There are many ambiguities in the Section 501(r) provisions that the IRS has yet to clarify in regulations, so many of the exempt hospitals seeking to get a jump on CHNA preparation may find their efforts prove inadequate, Griffith said. ''While hospitals that guess wrong may be forced to start again from scratch later, those that delay until regulations are finalized may find it impossible to meet the 2012 deadline for conducting the first CHNA,'' he added.

''In general, it appears that CHNAs will prove to be significantly more complex to conduct than anyone anticipated and that a lack of consistency in approach could frustrate efforts by Congress and patient care advocates to obtain the information they need to assess whether exempt hospitals are actually benefitting their communities,'' Griffith continued.

''While some hospitals may have drastically underestimated the time required to conduct an appropriate CHNA, an overly ambitious CHNA actually could make community conscious hospitals look worse if they fail to implement significant portions of the projected community need activities,'' he said. ''In addition, the IRS will be under increasing pressure to audit the reasons for non-implementation and to strictly enforce the requirement for a broad-based CHNA every three years.''

As a result of these complexities and concerns, Griffith predicted that more and more hospitals will develop a separate community benefit department with its own infrastructure similar to the development of the compliance function at hospitals in the 1990s.

The interest in ACOs and pressure to form them will not be without tax ramifications, Griffith continued. ''The IRS will likely struggle with the tax effects of ACOs and whether the community benefit of control-

ling cost and maintaining or improving quality of care that ACOs promise outweigh the private benefit provided to physicians who receive contracting, administrative and other services from the ACO and share in the savings,'' Griffith said.

He also predicted that IRS audits will be more common than other types of IRS investigations because of the IRS ''has a significant role in enforcing and implementing health care reform, including obligations of employers, employees, and nonprofit hospitals.

''The IRS will have plenty to audit with possible technical violations of the new requirements for 501(c)(3) status arising any time a billing clerk fails to give an 'economic Miranda warning' to an uninsured patient about the availability of financial assistance, or files a collection suit without turning over every stone to make sure the patient does not qualify for financial assistance,'' he said.

''At the same time, the IRS continues to express growing concern about traditional tax compliance areas such as excessive compensation, unrelated business income, and worker classification. In the past few years, the IRS has developed and become more efficient at compliance checks and follow-up exams that focus on limited issues and that blanket hundreds of hospitals,'' Griffith continued.

''Having done such projects on executive compensation and billing, collection and charity care in the health care industry, and unrelated business income and other issues for colleges and universities, the IRS has worked out many of the bugs in the process. It is likely that these compliance checks will accelerate and the issues examined at colleges and universities—particularly unrelated business income—will now be the focus of compliance checks in the health care industry,'' he said.

9. Corporate Governance. Health reform has made the governance issues health care organization managers and boards of directors even more complex, board members said. The prospects of ever increasing compliance oversight, and an unprecedented willingness on the part of state and federal enforcers to hold individuals accountable for compliance breakdowns, make the stakes of having weak governance policies and practices unacceptably high, they added.

A number of board members, including Raskin and Michael W. Peregrine, with McDermott Will & Emery LLP, Chicago, cited the risk of individual liability as one of the most important issues raising governance concerns. ''Individual liability of corporate executives is the number one issue as the specter of individual prosecution changes the enforcement negotiation dynamic, increases the government's leverage, and makes it even more critical than before that officers and management actively ensure the integrity and effectiveness of corporate compliance programs,'' Raskin said.

Peregrine said he also expects great pressure in 2011 on executives and board members stemming from increased federal regulatory pressure on those individuals the government believes are responsible for corporate misconduct. ''I believe this will be manifested in OIG actions to exclude executives responsible for noncompliant activities, CIAs which focus more closely on remedial action with respect to corporate governance and boards' compliance oversight obligations, and state charity regulator actions focused on directors perceived to have failed in exercising their compliance plan oversight obligations,'' he said.

Benesch said corporate governance has taken on new importance because of the emphasis the OIG has placed on the board's responsibility for institutional compliance. ''It is clear that the OIG will continue to hold hospital boards, administrators, and individual directors responsible for activities of the medical staff, senior administration and the billing office,'' she said. ''Claims made for substandard care now become a basis of prosecution under the False Claims Act and individuals become hospital trustees at their peril.''

Belmont agreed that there will be renewed focus on health care boards' oversight responsibilities in 2011 ''as a result of substantially increased enforcement activity and high profile settlements.'' She said health lawyers have to consider the need for health care organization governing boards to play a stronger compliance plan oversight role, noting that the OIG has, among other things, called for trustees to be more assertive in exercising their compliance oversight obligations and stressed the importance of providing the board with effective and open operational and compliance reporting systems.

Nahra cited ''the ongoing pressure in the health care industry and the substantial changes to the overall business environment from health care reform'' for making the role of the board ''increasingly important.'' While the pressures on board members are growing, because of the expanded challenges to engage in typical board activities and the expanded complexity of the health care environment, the government is looking to increase enforcement against senior executives and other individuals, he added.

''Individual liability of corporate executives is the number one issue. . .''

RICHARD RASKIN,
SIDLEY AUSTIN LLP, CHICAGO

Nahra agreed with Benesch that the role of serving as a health care organization board member may be losing its luster. ''Pressures on boards are growing, tensions between boards and management are likely to rise, and the 'benefits' of being a board member may not be able to keep pace with this development.''

According to Entin, payment reform and resulting changes to health care delivery will be significant challenges for those responsible for ensuring appropriate governance. ''Understanding the implications of new forms of relationships with physicians, competition with physicians, new forms of payment and necessary investments in the organization's future represents a huge learning experience to keep pace and govern the entity accordingly,'' he said.

Peregrine also noted that boards of nonprofit health care organizations will be under increased pressure to respond and answer to charity regulators at both the federal and state level as they take a closer look at the role of governance in connection with health care reform-related initiatives.

''The more the charity regulators understand about health care reform from the perspective of the nonprofit

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provider, the better able they will be to evaluate whether the board is serving as effective stewards of corporate assets,'' he said.

Peregrine predicted that 2011 also will see board and compensation committee members facing difficult decisions with respect to executive pay, given the current economic realities, and with respect to conflicts management, given that the role of a director-as-a-vendor has grown more unsustainable as a result of media scrutiny, regulatory inquiry, and Form 990 disclosures. ''Increasingly, health systems will be pressured to consider trust like standards which prohibit any material business or financial relationship between board members, their families and the organization,'' he said.

10. Labor and Employment. Labor issues will become more prominent in 2011, according to several HLR board members.

Although the ''card check'' legislation failed to pass Congress last year, union activity will nevertheless ''be on the upswing,'' Singer and Wall said. Wall attributes this increase to the tension between the ''pressure to lower costs [and] the need for qualified health care professionals.'' Kadzielski also sees increased union activity, but he attributes it to layoffs caused by the state of the economy.

John E. Lyncheski, with Cohen & Grigsby PC, Bonita Springs, Fla., said there will an ''uptick, and possibly a significant one, in union organizing in the health care sector in the coming year,'' in part because of a ''union-friendly'' National Labor Relations Board. Lyncheski said the Obama-appointed board members ''unquestionably lean extremely heavily in favor of organized labor.''

As a result, the board likely will issue decisions reversing ''significant NLRB precedent favorable to employers and/or establish precedent favorable to unions, particularly in areas facilitating union organizing,'' he said.

''It is also likely that the Board may pursue rule making and/or other administrative avenues that will speed up and/or facilitate the union election procedures,'' Lyncheski said.

There already have been ''a number of initiatives by appointees of the current administration . . . that will have an impact on health care employers,'' Lyncheski added. These include, but are not limited to, ''stricter and more aggressive enforcement of many labor and employment related laws.''

Lyncheski also believes an administrative law judge's (ALJ) recent decision involving the Florida Hospital of Orlando (*OFCCP v. Florida Hospital of Orlando*, DOL OALJ, No. 2009-OFC-00002, 10/18/10) will open the way for more government intervention into how health care facilities are run. Most health care facilities do not meet the requirements for them to be considered government contractors, Lyncheski explained. However, the ALJ's holding that the Florida hospital is a federal subcontractor by virtue of its participation in the military health care services program, Tricare, means that the Office of Federal Contract Compliance Programs (OFCCP) is ''a step closer to its goal'' of ''expanding the scope of its jurisdiction over health care providers,'' Lyncheski said.

''This ALJ decision will have significant implications in the labor and employment context,'' he said, since ''a significant number [of health care facilities] will now be considered'' to be government contractors as a result. ''Government contractor status has all kinds of negative and burdensome implications,'' Lyncheski said.

Also in the employment law context, several board members foresee problems arising from the aggregation and integration expected to occur in the health care field. Issues will flow from more hospital employment of physicians, for example, Benesch said.

Wall sees the likelihood of legal issues stemming from the physician shortage. He noted that the ''combination of an aging physician population, the surge of baby boomers who will retire over the next two decades and the newly insured will stretch the system beyond the limits.''

Crumel added yet another issue: immigration compliance. Although Crumel raised the question in terms of medical researchers, it easily could arise in other health care fields, especially given Wall's prediction that an ''influx of foreign medical graduates'' will help relieve problems caused by shortages of health care workers.

BY SUSAN CARHART, MARY ANNE PAZANOWSKI, AND PEYTON M. STURGES