



**BNA's**

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## Outlook 2010

### **Restructuring, Consolidation in Health Care Make Reform Top Health Law Issue for 2010**

**A**mong all the uncertainties surrounding pending health care reforms, one thing seems clear to BNA's *Health Law Reporter* advisory board members—reform will change, if not send shock waves through, virtually the entire health law field.

Board members asked to rank the Top 10 issues facing health care providers in 2010 overwhelmingly selected health care reform as the top issue. As Kirk Nahra said, "health care reform will dominate legal efforts in health care in 2010 and beyond as it significantly alters many of the areas of traditional practice." Nahra is with Wiley Rein LLP in Washington.

Fraud and abuse, Medicare, quality, and antitrust rounded out the top half of the list, followed by health information, taxation, health plan regulation, medical staff, and labor and employment in the bottom half. Most advisory board members agreed that health care reform would be an issue with reverberations throughout all of the others.

Fredric J. Entin, with Polsinelli Shughart PC in Chicago, said that practically every area of health law will be influenced in obvious and indirect ways by reform, other key legislative initiatives in Congress, and the implementation of legislation already passed such as the American Recovery and Reinvestment Act (ARRA). "While much of the focus has been on insurance reform, bills in both houses of Congress have provisions that would encourage the creation of new modes of delivery, enhanced collaboration between hospitals and physicians, and alignment of incentives to encourage necessary cooperation. Whether this really results in significant change to the health care delivery in the United States, there will be a raft of new matters for providers to consider," he said.

Richard Raskin with Sidley Austin LLP in Chicago sees reform driving significant industry restructuring and consolidation, while Howard Wall, at Capella Healthcare Inc. in Franklin, Tenn., predicted a surge in both mergers and acquisitions and health care financing. Gerald M. Griffith, with Jones Day in Chicago, said that as clinical integration increasingly is seen as having tremendous potential to create efficiencies and improve patient care quality, antitrust issues will loom.

Several advisory board members commented on the need for hospital boards of directors to take on increased governance responsibilities and warned that unless Congress modifies fraud and abuse laws to comport with the changes needed to make the nation's health system more effective and efficient, the resulting legal tensions will make work for providers and their attorneys for years to come.

To pay for reform, Congress is cutting provider payments but also zeroing in on fraud and abuse, recognizing, Nahra said, that fraud is a significant cost driver and that better anti-fraud efforts can help control costs. "With the new rules that will be generated as part of reform, there is the increased likelihood of a 'got you' enforcement approach, where the government can recover significant dollars from mistakes and errors in implementing the new rules," he said.

Mark A. Kadzielski with Fulbright & Jaworski LLP in Los Angeles said he sees this happening in the states as well. New laws and fines are "not a bad way to supplement a strapped state health budget," he said, as states take notice that California's laws on "never event" reporting enabled it to collect almost \$2.5 million in fines over a recent two-year period.

Elisabeth Belmont with MaineHealth in Portland, Maine, sees reform leading to substantial changes in existing health information and technology and its functionality in a range of categories.

Katherine Benesch with Duane Morris LLP in Princeton, N.J., said she sees an already difficult financial climate for hospitals and physicians being made worse by

### Health Law Reporter's Top 10 for 2010

Advisory board members ranked these the most important health law issues for 2010:

1. Tensions created by **health care reform** affect all other practice areas and make it the year's top health law issue.
2. **Fraud and abuse** continues to consume inordinate time and health lawyer resources.
3. New **Medicare** payment regimes focused on quality and efficiency impact providers.
4. **Quality**, the health care "Holy Grail," remains elusive.
5. Provider consolidation pressure stemming from reform and economic stresses keep **antitrust** hot.
6. **Health information** gets a HITECH shot in the arm.
7. IRS and state oversight of tax-exempt hospitals keeps **taxation** on the front burner.
8. **Health plan regulation** evolves in response to federal health insurance reforms.
9. Complicated **medical staff** issues continue to arise out of physician employment and peer review by hospitals.
10. Shortages of personnel in key areas and union activity dominate the **labor and employment** arena.

increased mandates for provision of care without the money to pay for them. "In addition," she said, "budget shortfalls in several states are forcing cutbacks in payments for Medicaid and hospital charity care, which is likely to lead to more hospital closures and unrest, as essential health care employees are laid off."

Wall said he sees medical malpractice reform "crawling back into the spotlight" while J. Mark Waxman, with Foley & Lardner LLP in Boston, said he anticipates reform driving reconsideration of alignment and the "startup of an entire series of health care transactions between physicians and hospitals, hospitals and hospitals, and ancillary providers as all are considering what is strategically required to be successful in the next phase of health care delivery and financing."

In all, board members agreed that 2010 promises to lead to the most radical changes for health care providers since Medicare came on the scene in 1965.

**1. Health Care Reform.** "There are at least \$849 billion reasons—the Congressional Budget Office estimate for the Senate bill's cost over 10 years—why health lawyers should be gearing up for health reform," Howard Wall said, adding that "lawyers will be in the middle of modifying employer health plans to incorporate reforms, unwinding and reworking physician-owned hospital deals, and establishing accountable care organizations (ACOs)."

Mark Waxman said that reconsidering alignment has hospital systems making decisions "to reduce their size, by either closing facilities, or cutting the cord of some hospitals to larger systems, or even transferring them to others. Physicians continue to form groups, or become employees of groups or hospital systems. Mergers and

acquisitions of hospitals continue to be much discussed."

Several board members commented on the media's focus on proposed insurance reforms. Jack A. Rovner with The Health Law Consultancy in Chicago commented that "since summer, when the president changed the subject from health reform to health insurance reform, reform has lost its cost and quality dimensions." Reform was supposed to address the "triple threat" to personal health and economic welfare—cost, quality, and access—but without a fix to the misguided fee-for-service payment system "promoted and protected most by Medicare, our nation cannot effectively solve the access or the quality problem," he said.

Kirk Nahra, too, was doubtful about current efforts. He said that their partial nature means the nation is "not going to solve the health care problem, and lawyers will be dealing for years with what else needs to be done and how the government will pay for it."

Board members applauded reform's major goals: increasing access to needed health care services, promoting provider coordination and integration, supporting a stronger role for primary care and improving care for people with chronic conditions or complex needs, holding providers more accountable for results, and increasing health system efficiencies. They debated, however, whether current initiatives would bring these changes about and whether congressional proposals will just create more problems down the road.

Citing the unsustainability of "runaway" health care costs, including in the Medicare and Medicaid system, "with its many medical errors, poor outcomes, misuse of resources, uncoordinated episodes of care, and payments that reward volume not value," Douglas A. Hastings, with Epstein Becker & Green PC in Washington, said reform should focus on the payment and delivery system, "the real engine of true, long-term improvement in both the effectiveness and efficiency of care."

This cannot come a moment too soon for Douglas Ross of Davis Wright Tremaine LLP in Seattle. He sees legislators continuing to search for the "payment unicorn." Two decades after diagnosis related groups were introduced, "we continue to believe that if we try hard enough, we can perfect a system of administered prices and solve the affordability problem. Today's notions encompass plans to move from pay-for-procedure to pay-for-performance; more demonstration projects on ACOs; the 'medical home' idea; a return to discussions of capitated payments and other forms of sharing financial risk/rewards, etc., each of which fixes some problems while creating others," Ross said.

Stephanie W. Kanwit with America's Health Insurance Plans in Washington called payment reform "critical," saying the legal system must eliminate barriers to innovative payment models that promote quality while making care more affordable. Models may include bundling payments for better management of chronic conditions, designation of a medical home, incentive programs to coordinate care and develop patient-centered care, and global case rate models, she said. Also "on the table for the future is updating the Medicare physician fee schedule and instituting a transparent, public process that can be adjusted for gains in efficiency and provider productivity. Look also to see measures introduced that help set (through regulatory and other means, like licensure, certification and accreditation)

minimal threshold performance levels for health care organizations and professions,” Kanwit said.

Many board members said they worry that the aggressive enforcement of current Medicare fraud and abuse laws will hamper needed payment system innovations. Others said they worry about the proliferation of burdensome regulations.

Robert L. Roth with Crowell & Moring LLP in Washington said he expects increased enforcement in the Medicaid program because “the federal government and the states have spent the past couple of years building a vast Medicaid enforcement infrastructure, which moved in 2009 from planning to implementation. Look for that trend to accelerate in 2010.”

Wall, like others, expressed concern about the rise of even more cumbersome regulatory systems and predicted reform will “add yet another layer to the already burdensome system of federal and state regulation that makes the business of health care more difficult with each passing year.” The Health Insurance Portability and Accountability Act (HIPAA), the Emergency Medical Treatment and Labor Act (EMTALA), state certificate of need (CON) and licensure issues, Centers for Medicare & Medicaid Services (CMS) reporting requirements, new rules for patient safety organization, Federal Trade Commission (FTC) red flag security rules all are examples of how new layers of regulation are added or increased without eliminating existing ones, Wall said. In evaluating the real reason why health care costs almost 17 percent of U.S. gross national product, he said, “maybe the answer lies not just in excessive jury verdicts or billing fraud, but in the administrative burden of excessive, duplicative regulations.”

Kanwit agreed. “There’s a concern about the regulatory complexity created by proposed reforms that create an entirely new federal system of insurance regulation instead of building on the state regulatory system,” she said. She gave the example of the proposed Affordable Health Care for America Act (H.R. 3962), which would duplicate oversight in many areas already highly regulated by the states, such as coordination of benefits, external review, and prompt pay. “The question is when overlapping regulations simply create confusion and complexity and unnecessarily raise costs,” Kanwit said.

John D. Blum of the Loyola University Chicago School of Law cited problems even with existing provider regulation, saying “far greater clarity needs to be articulated by state and federal regulators over issues involving safety net matters such as EMTALA, charity care, and even CON statutes.” Existing CON laws should be tailored only to these matters, Blum said.

Michael W. Peregrine with McDermott Will & Emery LLP in Chicago said the collection of anti-fraud provisions and quality-of-care rules in pending proposals will increase the work of hospital compliance committees “exponentially.”

Eric A. Tuckman, with the Advisory Health Management Group in Irvine, Calif., said he sees Medicare reimbursement issues “exploding” as health reform changes the current payment scheme. “This will become especially important to safety-net hospitals as federal and state disproportionate share programs are redefined or eliminated,” he said. It is even possible that traditional Medicare reimbursement advocacy will find health providers taking a much more active role in im-

migration reform in order to qualify patients for coverage under the new system, he said.

Doug Hastings said that changing Medicare and Medicaid to bring about a more coordinated and patient-centered health care system will trigger private market changes as well. “We have a mixed public/private system for powerful historical reasons. Even the congressional debate about federal payment changes stimulates change in the private market,” he added.

Katherine Benesch cited the worsening financial climate for hospitals and physicians as mandates to provide care increase with no increases in monies to pay for the services rendered. “On the physician side, practitioners have been fighting to maintain past reimbursement levels in the face of multiple efforts by insurers to reduce them. In some states, physicians report that decreased reimbursement levels are leading their colleagues to move to states with higher payment rates. Much of this activity appears to be in anticipation of increased federal regulation,” she said.

Thomas Wm. Mayo at Southern Methodist University Dedman School of Law in Dallas expressed concern about reform’s effect on the states. He called the Medicaid program “a budgetary balloon that is about to burst,” exacerbated by the recession and by mandating increased access to the program without helping states with their matching share. Given this “unsustainable burden, health reform is likely to make matters worse for the states, not better,” he said.

Ross said he also sees fallout from greater care access: “Physician shortages and crash programs to expand medical education; turf fights over the scope of practice of nurses and other paraprofessionals; and efforts of specialists vs. primary care practitioners to ‘reform’ to their advantage physician payments under Medicare’s relative value scale and other insurance schedules.”

Elisabeth Belmont also expressed concern about providers, particularly hospitals in states like Maine, where she is hospital counsel. To pay for the coverage expansion that is a main goal of reform, all the proposals under consideration cut Medicare home health and hospital reimbursement, she said. “But this does not equate to sustainable long-term cost savings for states like Maine, which already has the second lowest hospital reimbursement rate.”

Blum said state programs will need to be significantly revamped as current models “simply may not be sustainable even with new revenues. This will not be just a state-based problem, but will filter down to county governments as well.”

Rovner said he expects that states will be forced to do what Congress has failed to do—tackle cost and quality “by moving more and more away from fee-for-serve into managed care like the original HMO model that shifts financial risk to providers forcing those willing or required to take Medicaid to invent processes that earn profit through quality and efficiency, rather than volume and waste.”

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### **“We have a ‘perfect storm’ in health care fraud.”**

KIRK NAHRA, WILEY REIN LLP, WASHINGTON

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Rovner added that, “unless the industry as a whole—physicians, hospitals, payers, and others—break out of

their silos of self-financial interest and heal themselves, Congress and the president will have to confront the real issues of our failing national health care delivery system in years to come.”

But Sanford V. Teplitzky, with Ober Kaler, Washington, pointed out that existing fraud and abuse laws generally require the “siloeing” of health care providers while health reform encourages and incentivizes cooperative efforts to improve care and reduce costs. To date, he lamented, there have been no serious proposals to amend the statutes in a manner that would let providers work together without violating the law.

**2. Fraud and Abuse.** Fraud and abuse remains high on the Top 10 list, board members said, because of the legislative enactments, health reform proposals, and complex compliance challenges that perennially vex providers.

While health system reforms, likely to include funding for an increased number of investigations and prosecutions, are sure to spur government enforcement increasingly geared toward using huge fraud recoveries to offset the cost of other initiatives, whistleblowers wait in the wings with new tools and ammunition that could skew enforcement priorities and, in many cases, confront providers with battles on multiple fronts, they said.

Kirk Nahra summed up the concerns of many board members. “We have a ‘perfect storm’ in health care fraud,” he said, a clearly aggressive administration, changes to the False Claims Act that will drive a variety of new whistleblower cases, and a growing recognition that fraud is a significant driver of health care costs.

This will put even more pressure on the government to make good on its anti-fraud commitments, Nahra said. “They will be looking for even more extensive and aggressive and creative ways” to generate money for government health insurance programs from health care providers and others, he said.

Mark Waxman agreed that fraud and abuse issues remain a challenging reality for providers who may find themselves far too easily tripped up by the Stark rules, new rules on conflicts of interest in many states, and the federal Civil Monetary Penalties (CMP) statute. “This means that the threat of enforcement under the recently amended FCA is always lurking and that a truly ‘living’ compliance plan remains an essential element of daily operations,” he said.

Doug Hastings said he sees the tension between the collaboration needed to attain efficiencies and fraud and abuse concerns as continuing to grow as health care reforms are implemented. “The challenge for the enforcement community will be to determine what is a ‘good’ incentive between a hospital and physician to encourage proper use and what is a kickback disguised as a proper incentive,” he said.

Eric Tuckman said the need to facilitate collaboration between physicians and health care organizations “will require the enactment of clear safe harbors and guidelines to induce organizations and their leaders to enter the vague, poorly defined, and often uncharted waters of physician/hospital economic relationships.”

The expansion of government-sponsored hot lines and websites encouraging whistleblowers “will undoubtedly increase both regulatory activity and criminal prosecutions,” Tuckman continued. “We are also likely to see activities that have in the past been recog-

nized as ‘accepted practice’ challenged in government proceedings and in qui tam actions.”

Howard Wall pointed to the Department of Health and Human Services Office of Inspector General’s Fiscal Year 2010 Work Plan, calling it “required reading” for all health lawyers. The importance of the work plan “is like the college professor who gives you the final exam with all of the answers ahead of time. All you have to do is actually study,” he said.

“The focus on hospital readmissions, denial of payment for ‘never events,’ and the long-term impact of the Recovery Audit Contractors (RACs) are just a few of the things that providers will need to worry about in 2010. In addition, the OIG and U.S. attorneys are going to increase focus on quality issues while areas such as physician contractual arrangements will continue to receive scrutiny,” Wall added.

Katherine Benesch said, “Government prosecutors have made gleeful and boastful presentations during the past year about their increased activity in the civil and criminal prosecution of health care providers for treble damages. Much of this is made possible by the linkage of prosecution under the FCA with violations of the Stark law.”

“Continued amendments to the Stark law and its regulations have increased confusion in this already complex area and made it difficult for providers to feel secure with the organizational changes they must make every day. Meanwhile, in the states, new offices of insurance fraud prosecutors are flexing their muscles and using state police powers to root out billing ‘fraud,’ whether it results from intentional bad activities or not,” Benesch added.

Richard Raskin noted that, with the likely enactment of more stringent fraud and abuse provisions and dozens if not hundreds of cases already in the pipeline, “expect another busy year in enforcement.” The industry also should expect “more pharma settlements, more medical device cases, and more corporate integrity agreements for all types of health care companies,” he said.

Fred Entin cited new patient care and payment models coming out of reform efforts that will give providers greater responsibility for coordination of care, creating incentives to focus on outcomes not just procedures and demanding greater integration of hospitals and physicians.

“In the absence of regulatory reform, the thrust for quality-oriented relationships and incentives will require carefully designed programs to comply with Stark and anti-kickback restrictions and, especially, the CMP proscription against reducing or withholding care,” Entin said. Despite OIG advisory opinions on pay-for-performance programs implicating the CMP, “the OIG’s literal reading of the statute remains a hurdle if not a barrier to programs that include gainsharing initiatives,” he said.

Entin also cited FCA amendments that give enforcement agencies another serious tool to combat fraud and abuse. “The most important of the amendments to the False Claims Act enacted in the Fraud Enforcement and Recovery Act (FERA) confirmed by statute that there can be liability for failure to return payments or overpayments the provider knows or should know he is not entitled to,” Entin said.

“Another issue worth watching in 2010 is how to handle the disclosure of Stark violations now that the

OIG has ‘closed’ its self-disclosure program to the Stark law. Considering increased liability for reverse false claims and the ramp up of RAC, Medicaid Integrity Contractor, and Zone Program Integrity Contractor audits—which will be in full force for the entire country this year and should encourage self-auditing—2010 should prove to be interesting for providers who will need to determine what to do with self-discovered overpayments,” Entin said.

Sandy Teplitzky said that, while he did not anticipate any significant regulatory changes in the Stark landscape during 2010, he did suspect that 2010 would see a number of investigations and enforcement efforts aimed at alleged Stark violations.

“My concerns in this area focus on the fact that government investigative priorities are being driven by the filing of relator actions under the FCA and that the issues that will be addressed in the coming year may not be the most important ones, but will most likely be those identified by individuals who may seek personal financial gain over the public interest,” he said.

“With the passage of state false claims statutes, we have seen, and I expect that we will continue to see, actions brought in multiple states at the same time. Although the National Association of Medicaid Fraud Control Units has attempted to coordinate state investigations and resolutions, I suspect that many states will ‘go it alone,’ which will make it extremely difficult for companies that operate in more than one state, since they will find themselves under attack from multiple directions at the same time,” Teplitzky said.

“I anticipate that 2010 will be an active one for everyone whose lives are touched by the issues of fraud and abuse, including federal regulators and enforcers, relators, health care providers, and their counsel. I only hope that some sense of calm, reasonableness, and rationality will serve to ensure that legitimate efforts by health care providers who are operating in good faith to improve care and reduce costs are not caught up in what can be devastating and career ending investigations, often initiated by those simply seeking ‘fortunes at the end of the qui tam rainbow,’” he concluded.

Michael Peregrine pointed to governance implications of fraud enforcement, saying he expects a continuation of the trend toward placing more fraud and abuse compliance responsibilities in the hands of corporate board members. 2010 will be “particularly active in terms of regulatory scrutiny of hospital boards’ exercise of their compliance plan oversight obligations,” he said. “This is particularly the case if other states follow New York’s lead and place an affirmative compliance plan certification obligation on the boards of state Medicaid providers, with penalties for board members who do not exercise effective oversight,” he said.

“The OIG has been a strong advocate for effective compliance plan oversight by boards, and I anticipate that a particularly bad fact pattern involving director malfeasance will present itself, offering OIG the opportunity to hold the board accountable in a very public manner,” he added. At the same time, “general counsel in particular will want to be attentive to any further expansion of the responsible corporate officer doctrine in health care, beyond its most recent application in the medical device and pharma areas,” he advised.

Elisabeth Belmont agreed. “DOJ and private whistleblowers have increasingly used the FCA to address egregious failures to oversee or provide quality care,

employing creative new legal theories that argue that billing for substandard services is either ‘false certification of compliance’ or tantamount to billing for a ‘worthless service,’” Belmont said.

“The government’s enforcement efforts are also increasingly targeting individual officers, directors, and medical staff leadership who fail to fulfill their fiduciary and other obligations to effectively oversee the quality of care rendered in the hospital,” she said.

Bob Roth said that, in the end, fraud enforcement was the only area where there was not “more talk than action” in 2009, and “it is hard to imagine any future administration reducing this focus given the trillion-plus dollars spent on federal health care programs.”

**3. Medicare.** Based on its sheer size and lead role in regulation, Medicare—including implementation, reimbursement, funding, and drug benefits—is a focal point for health care reform and will continue to be an important health law practice area in 2010, advisory board members said.

The federal insurance program has become the dominant cost and attention driver for the entire health care system, Kirk Nahra said, leaving it an open issue how much of any new system will be driven by Medicare or combined with or compared to Medicare. Also an important issue is the effect of Medicare payment cuts, Bob Roth said. Current bills cut nearly \$500 billion from the program and it is possible that many of these cuts will pass even if other reforms do not, Roth said.

John Blum said Medicare should be cut not only on the physician and hospital sides but that, like Medicaid, all aspects of the program will need to be rethought and changes, particularly those that would phase out fee-for-service reimbursement perhaps replacing it with bundled episode-of-care-based payments, will have to be installed.

Jack Rovner vigorously agreed. He said changes are needed in physician reimbursement limits set by the “sustainable growth rate,” which seeks to stop Medicare from growing faster than the economy as a whole and which, according to some economists, would need to be cut today by more than 40 percent to fulfill this objective. Change also is needed in the overall payment scheme for Medicare Parts A and B. This, Rovner said, has to move away from fee-for-service “volume rewarding” to an economically sustainable payment mechanism that provides incentives for quality and efficiency. Congress, however, “has shown no fortitude to take the issue on, the Obama Administration no leadership to meaningfully address the provider community, and the health insurance industry no courage to stop following Medicare as the way to pay” and instead innovate with better provider payment processes.

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**“We will soon reach a tipping point  
on the road from volume to value.”**

DOUGLAS A. HASTINGS,  
EPSTEIN BECKER & GREEN PC, WASHINGTON

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T.J. Sullivan of Drinker Biddle & Reath LLP in Washington, however, said he believes provider rate cuts “may actually have a chance of being implemented this

time, but not before the last round of physician payment cuts is wiped off the books, with or without an offset. If seniors are lucky, they may see relief from paying retail for drugs in the 'doughnut hole.'” Lawyers, doctors, and other highly paid individuals, he said, all will see higher Medicare taxes withheld from their paychecks to help pay for reform. “Over the next several years,” Sullivan added, “I see higher taxes trumping benefit cuts.”

Rovner said he sees the likely congressional fix to Medicare Advantage (MA) being the elimination of payment benchmarks above Medicare fee-for-service and the fix to the access problem being a public plan option that is “likely to shake up the health insurance and employer benefits markets. There will be lots of losers as these market changes eclipse the ability of many incumbent insurers and third-party administrators to restructure their business models. But for the few with vision, courage, speed, and agility to adjust, the business opportunities in changes to MA, the Medicare Part D prescription drug program and, yes, even the public plan, are likely to be profound.”

Fred Entin expressed concern about Medicare cost-shifting. “Everyone concerned about affordable coverage needs to be concerned about this,” he said. Since Medicare and Medicaid significantly underpay hospitals and physicians, it adds about \$1,500 annually to the premiums for an average family of four, he said.

Stephanie Kanwit said she sees problems with changes proposed for Medicare Part D in the name of transparency. Some harm competition by prescribing specific terms for what should be arms-length commercial dealing between insurers and service providers, chilling negotiations that otherwise would be a win-win for both parties, she said. “It makes no sense to create inflexibility on both price and non-price contract terms,” Kanwit said. “Nor does it benefit consumers to allow identification of protected formulary classes in Part D, which only makes affordability harder to achieve.”

Vickie Yates Brown, of Frost Brown Todd LLC in Louisville, Ky., summed up the Medicare picture this way: whatever the mechanism chosen, the bottom line is that Medicare costs “must be brought under control as costs continue to increase and more baby boomers qualify for coverage.”

**4. Quality of Care.** Few topics garnered more board member comment than improving the quality of care in American hospitals. Advisory board members cited the growing recognition that, as Bob Roth said, the “‘paymentization’ and ‘compliance’ of quality has made it a vehicle that can deliver savings, particularly to Medicare.”

Jack Rovner said he sees this vehicle virtually stopped this year. The reforms enacted by Congress—not, he said, health care reform but health insurance reform—will prove “utterly ineffective at bending the health care cost curve, promoting quality, or even solving access because insurance reforms fail to make what the expanded insurance pays for affordable.” This means that another Congress “will be forced to confront the real issue—that changes addressing cost and quality problems are the only effective way to improve access,” Rovner said.

But Tom Mayo said that, with reimbursement increasingly tied to quality care, hospitals themselves are “finally starting to compete in a serious way over qual-

ity issues.” Howard A. Burde with Howard Burde Health Law LLC, Wayne, Pa., said a study comparing cost and patient outcomes in the Texas cities of McAllen and El Paso grabbed the attention of both the White House and the public by showing that spending twice as much per Medicare beneficiary did not result in better outcomes. This and similar findings support giving quality a central role in reforming the payment system, he said. Howard Wall added that the expansion of public reporting measures by CMS, and some states, and the promotion of CMS’s “Hospital Compare” website are further evidence of the increased focus on patient care quality.

Burde also observed that the OIG, Joint Commission, Department of Justice, and CMS “all have gotten on the quality bandwagon, once the turf of state regulators.” Despite the “ill-timed report” on the effectiveness of mammogram screening in late 2009, evidence-based medicine based on comparative effectiveness research (CER) is likely to become the basis for payment, at least under government programs, he said.

Doug Hastings said evidence-based medicine can scientifically define “overuse, under-use, misuse, and, through broadly adopted measures, proper use.” As both public and private payment mechanisms adapt to using such measures in a comprehensive way, and delivery systems organize to deliver care in a clinically integrated and coordinated manner, “we will soon reach a tipping point on the road from volume to value,” he said.

Mayo, however, cited “the hue and cry over the breast cancer-screening recommendations as a good example of how a large number of us view CER and the trade-off of dollars and statistical lives when that trade-off affects our own care and health.” And John Blum—who asked, “Whatever happened to patient safety, as a focal point in the quality area?”—called CER a “recycled concept that needs to be proven.” Also, he said, while “novel quality structures like ACOs that tie into value purchasing are still too new, they raise interesting reimbursement, antitrust, and licensing questions.”

Elisabeth Belmont and Stephanie Kanwit both said payment systems should reward better clinical outcomes, improved patient experience, and lower total costs of care. But both also see impediments to quality-based reimbursement. Belmont said current proposals largely fail to address the limited base of evidence to improve care and the limited infrastructure to spread best practices once they are identified. Kanwit said reformers will have to discover how to “close the gap between what scientific evidence shows and what is actually practiced,” and create incentives for a more effective and coordinated delivery of services.

Belmont sees incentive programs, both public and private, gaining increasing traction as payers seek to leverage their premium dollars to produce better, more efficient care. “On the incentive side, financial pressure is being exerted through the increasing use of quality-based ‘pay for performance’ initiatives,” she said. The penalty side of pay-for-performance is exemplified by CMS’s “never events” payment policy and its state analogues, which withhold payment for “allegedly substandard care.” Mark Kadzielski cited a recent development in Rhode Island, where a hospital with frequent wrong-site surgeries was required to put cameras in its operating rooms. It is “punishment” and “more Draconian

than monetary fines,” he said, but will have an even greater effect on quality.

Mark Waxman said efforts to deliver quality are “driving an emphasis on systems, including an IT infrastructure necessary to measure and educate about quality,” a development that may have collateral effects in the regulatory and antitrust arenas as providers strive to deliver quality across entity boundaries, he said. All of this is likely to come together in health plan regulation and also lead to reconsideration of the Stark and anti-kickback rules, he said.

According to Eric Tuckman, in the relatively non-consolidated hospital market segment, attaining significant quality improvement and cost efficiencies may be achievable only through the type of operational integration normally associated with mergers and affiliations. “Redesigning clinical and administrative processes requires sophisticated organizations and operational techniques and policies often better accomplished by well-developed regional and national health care systems,” he said.

Changes also will affect the responsibilities of hospital boards of trustees. Katherine Benesch said she sees corporate governance taking on new importance for hospitals as “federal and state governments push this lever in their attempt to improve oversight of the quality of care” rendered by hospital staff. “A few years ago, it would have been unheard of for hospital administrators and board members to be prosecuted by the DOJ or the OIG for failure to exercise oversight of care rendered by physicians practicing at the hospital. But such prosecutions are increasing.”

Last year, Benesch said, an advisory board member wondered if patient safety and quality of care would be “sacrificed on the altar of economic recovery efforts.” This past year, she continued, “we have learned that resourceful federal bureaucrats and regulators will levy heavy fines under the FCA amounting to billions of dollars for lack of compliance with quality of care and billing standards.”

“One could argue that this may increase quality. On the other hand, extracting this many resources from health care delivery could decrease the quality of services a provider or institution is able to render,” Benesch added.

Several board members commented on increased board responsibility, with Waxman saying that boards “must take more time than ever before to direct overall strategy management.” But Blum said realistic expectations of voluntary boards have not yet been clearly determined and “increasing board responsibilities for quality remains an illusive, and, in some cases, unrealistic focal point.”

Kanwit looked at another aspect of better patient care. What is needed, she said, is a way to “stop the flow of dollars wasted on defensive medicine and in a medical liability system that doesn’t accomplish goals for either patients or physicians.” Suggestions include moving medical malpractice cases into health care courts or before medical review panels that will screen out frivolous suits, employ early-offer programs, and create safe harbors for reporting errors if providers have acted in accordance with evidence-based guidelines. Wall said funding for state pilot projects to use health courts and other innovative ways to resolve liability claims may indicate “the grip of the trial lawyers

to block any changes to the current tort system may be slipping a bit.”

**5. Antitrust.** Antitrust law concerns come to the fore again this year, board members said, because of the confluence of the heightened scrutiny and more vigorous enforcement agendas of federal agencies and because of consolidation and integration pressures stoked by continuing economic uncertainty and the quality enhancement and cost-containment mandates underlying health reform proposals.

Activities implicating competition and antitrust laws—and their enforcement—also will spill over as new provider collaboration, practice, and reimbursement models are implemented and industrywide initiatives, such as health information technology (HIT) adoption, mature, they added.

According to Toby G. Singer, with Jones Day in Washington, federal enforcement will be heightened because of a resurgence of merger activity and new FTC and Department of Justice appointees look “for an opportunity to make their mark and distinguish themselves from the Bush administration.” Singer said she expected the FTC to continue its emphasis on reviewing consummated health care mergers and that DOJ, for its part, “will be looking for the right health plan transaction to challenge given the (probably unfair) criticism they have gotten for failing to challenge more transactions than they have.”

Doug Ross said he, too, expects more antitrust enforcement and more private antitrust litigation as a result of a combination of payment reform efforts, an increase in physician demand for employment-type arrangements, physician shortages, and pressure on single community hospitals to affiliate with systems.

Richard Raskin agreed, saying he expects “a busy year in health care antitrust because new leadership at the FTC is clearly committed to pursuing enforcement actions against pharmaceutical and medical device manufacturers while providers, too, are likely to face enforcement pressures as they attempt to restructure their businesses to respond to reimbursement pressures and health care reform.”

Raskin added that, “with a new chair and two new commissioners on board, the agency may pursue new theories of liability, including theories that extend Section Five of the FTC Act beyond the limits of Sections One and Two of the Sherman Act.”

Jack Rovner said quality improvement and cost containment pressures will lead a push for more collaborative endeavors, such as “medical homes” and ACOs to test coordinated and integrated care models and global payment processes, which will in turn lead to more enforcement and calls for more guidance.

“There will also likely be provider pressure on antitrust agencies to issue bright-line guidance on the kind of clinical integration that is not vulnerable to antitrust attack and increasing pressure on Congress for antitrust exceptions to permit collaboration among independent, competing providers,” Rovner said.

**“Cooperation between physicians and hospitals will be risky and out of the reach of providers who are not financially integrated.”**

FREDRIC J. ENTIN, POLSINELLI SHUGHART PC, CHICAGO

According to Doug Hastings, antitrust will remain a significant compliance concern because the enforcement community is likely to struggle as it learns how to vigorously prosecute improper actions without discouraging activities needed to adapt to health care system changes.

“Given that the goal of reform is better coordination and cooperation among providers, regulators will have to be able to distinguish the ‘good’ from the ‘bad,’ ” he said. “Which hospital mergers promote sufficient clinical quality, even if they reduce competition, to be allowed to proceed? Which do not?”

“The government, as purchaser, wants more cost effective health care delivered for those patients it covers and wants providers to collaborate to bring that result about. But as regulator, the government wants to make sure that such collaboration does not involve agreements to restrain trade,” Hastings said.

“Enforcing against monopolistic activity by an individual or entity is broadly supported and raises few concerns as a general concept. Getting the balance right when judging ‘good’ collaborative behavior from ‘bad’ as between independent parties in this era of health care reform will, however, be tough,” he added.

Eric Tuckman said 2010 will be “a defining moment” for hospital antitrust enforcement, but said that the recent increase in governmental scrutiny and adverse regulatory decisions in high profile merger cases only marks the implementation of what has long been anticipated as an expected fundamental change in government antitrust enforcement policy.

Now, he said, “the government’s challenge in adopting its revised policy will be to reconcile traditional antitrust analysis with current health reform policy objectives to allow and facilitate the major objectives of health care reform: cost reduction and quality improvement.” Enforcement policy will have to be flexible enough to allow efficiencies even if they come with additional market concentration, he concluded.

Fred Entin said he expects pressure for change in hospital physician relationships to have significant antitrust ramifications in the coming year.

“Physicians may be more willing to be employed by hospitals than they have in many years, but in 2010 and for the foreseeable future, most physicians will remain in private independent practice or as members of group practices. While employment creates the financial integration necessary to collaborate on many of the incentive-based arrangements, cooperation between physicians and hospitals will be risky and out of the reach of providers who are not financially integrated,” Entin said.

“Clinical integration in the absence of financial integration has been gaining acceptance by the FTC and many consider it critical to the adoption and use of HIT as the monitoring and measuring of the efficiency of the

clinically integrated practices is heavily dependent on the power of computing technology,” Entin continued.

“Although clinical integration may not have been considered years ago as a platform for pay-for-performance and other quality improving and incentive based programs, it does create a platform ideally suited for these programs. More organizations, particularly where there are strong relationships already between providers in the community will likely be exploring these opportunities,” he said.

Stephanie Kanwit said she was concerned about efforts to repeal portions of the McCarran-Ferguson Act that “seem to be based on a misperception that somehow health and medical malpractice insurers have been ‘immune’ from the federal antitrust laws when, in fact, all insurers are and have always been subject to state antitrust laws.”

She also questioned why Congress would want to repeal those portions of McCarran-Ferguson and create regulatory uncertainty “that may be counterproductive, in that it may chill efforts that are already underway—such as those proposed to aggregate data across health insurers so that physicians aren’t evaluated only through the lens of an individual health plan’s patient population—to benefit providers and consumers.”

**6. Health Information.** Board members cited health information as a key Top 10 issue because of the promises it holds to improve quality and achieve cost-containment goals and because of the legal challenges it poses for lawyers throughout the health care delivery system. “No area offers more upside to improved population health nor is fraught with more thorny legal issues” than health information, Doug Hastings said.

A number of those issues, according to board members, will be raised by the Health Information Technology for Economic and Clinical Health Act (the HITECH Act), enacted as part of ARRA.

The HITECH Act contains several provisions that will affect providers in 2010. First, the act authorizes a \$36 billion investment in health information technology (HIT) and health information exchange (HIE). This, according to Elisabeth Belmont, “has the potential to facilitate significant change in the health care industry through new incentives to adopt HIT and establish HIE to improve the quality and efficiency of health care while decreasing its cost.”

HIT issues “will rise to the forefront” due to the law’s funding provisions, Toby Singer said. Fred Entin observed that “ARRA certainly has thrown massive amounts of government support behind the acquisition and adoption of HIT by physicians and hospitals alike.”

But Katherine Benesch questioned whether this will be enough to cover the costs of the “huge endeavor” needed to convert physician office record-keeping systems from paper to electronic form.

Jack Rovner seemed to agree. “ARRA and other government financial incentives don’t seem to have yet lit much of a fire in providers who remain vexed by the cost (regarding technology acquisition, installation, and practice process disruption), complexity, and general ineffectiveness of the electronic health record ‘solutions’ in the market.”

And, while Kirk Nahra said he sees real possibilities in a “dramatically broadened increase in HIT use and the exchange of health information,” he cautioned that “these efforts are very complicated and very expensive

and the connection between their cost and any measurable savings are imprecise at best.”

Howard Burde said he believes the distribution of ARRA funds to states and providers in itself to raise many legal issues while Doug Ross said simply that HIT, “the supposed ‘glue’ and ‘grease’ that would make payment reform and delivery system reform possible, will continue as a sinkhole for taxpayer dollars.”

The HITECH Act also significantly expands HIPAA privacy and security rules and increases the penalties for HIPAA violations, Belmont said. According to Richard Raskin, health care providers will be busy in the coming year developing new systems and protocols to ensure HITECH compliance.

Mark Kadzielski agreed that HIPAA and HITECH issues will become more visible in 2010. And both Stephanie Kanwit and Bob Roth predicted that HIPAA enforcement will become more intense. In particular, focused audits and other enhanced enforcement activities, including criminal investigations, are likely to increase in 2010, Raskin said.

One change in the law that caught the attention of almost all the commentators was the adoption of a new breach notification rule and its application to “business associates.”

Belmont explained that the HITECH Act, for the first time, imposes mandatory breach notification obligations on HIPAA-covered entities. Under the rule, an entity that suspects a privacy breach must notify each individual “whose unsecured PHI [personal health information] has been, or is reasonably believed . . . to have been, accessed, acquired, or disclosed” as a result of the breach.

A similar requirement applies to a “business associate,” an entity that “accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured” PHI, Belmont said. Business associates now must provide notice to the covered entity, including “the identification of each individual whose unsecured PHI has been, or is reasonably believed by the business associate to have been accessed, acquired, or disclosed during such breach,” she added.

The new act allows providers and other HIPAA-covered entities to “flex their muscle in their business associate agreements” because business associates now may use or disclose PHI only in compliance with each applicable requirement of 45 C.F.R. Section 164.504(e) and now will be directly responsible for fully complying with the relevant requirements of the privacy standards and subject to civil and criminal penalties if they fail to do so, Belmont said.

W. Reece Hirsch, with Morgan Lewis & Bockius LLP, San Francisco, predicted that, in the early months of 2010, “there will be an industrywide fire drill to amend thousands of HIPAA business associate agreements to comply with the HITECH Act requirements.” Also, he said, “HIPAA business associates will find it a formidable task in 2010 to develop and implement the necessary data security compliance programs, obligations complicated by a lack of guidance from the relevant agencies.”

Jack Rovner said he has seen “few signs that the industry . . . [is] sufficiently prepared or preparing” for the Feb. 17 effective date of the breach notification and business associate rules. However, Stephanie Kanwit said she has noted “efforts by health plans, providers, and clearing houses to implement the updated HIPAA

electronic health care transaction standards, which have a Jan. 1, 2012, deadline.”

Belmont questioned whether these privacy laws go far enough. She cited a study in which researchers were able to identify individuals from electronic data that had been stripped of personally identifying details, “raising questions about whether the newly strengthened laws governing electronic health records offer incomplete privacy protection.”

Kadzielski finds the self-reporting provisions troubling. “The self-reporting of privacy breaches mandated by these new laws does not deter, but rather encourages governmental investigations and fines,” he said. “Health care providers are also caught between the proverbial rock and a very hard place in making disclosures to patients of their privacy breaches, since patients are less understanding about such errors than they are about clinical mishaps.”

Nahra speculated that pressures on health care privacy could ensure that efforts to implement HIT are “less successful than they could be.”

In addition to technology and privacy concerns, health care providers should be aware of new restrictions on the use of health information imposed by the states. Belmont noted, for example, “more stringent state limits on the ability of pharmaceutical companies and others to use prescription data for marketing purposes.”

Howard Burde added that it “will be fascinating to watch” state creation of health information exchanges. “Every state is busy doing something,” he said.

**7. Taxation.** Board members said they will remain focused on tax issues during 2010 as Congress and state and federal regulators continue their search for ways to define, if not quantify, community benefit and charity care in the exempt hospital context and as the Internal Revenue Service continues to build on initiatives designed to obtain and utilize data—on executive compensation, excess benefit, governance, and other areas of concern—provided through Form 990 filings and IRS investigations.

Board members said they also remain concerned about the effect that economic pressure on state governments—whether stemming from Medicaid funding shortfalls or general economic dysfunction—could have on the treatment of exempt hospitals under state property tax assessment schemes. Several suggested that, depending on the outcome of the Provena Covenant case in Illinois, other states could decide to follow the lead of Texas and Pennsylvania in demanding that exempt hospitals use a set percentage of their revenue to provide charity care.

Mark Waxman said he expects continued scrutiny of hospital exemption and nonprofit hospital operations fueled in part by the ongoing interest of Sen. Charles Grassley (R-Iowa)—and parallel interests at the state level—asking, “What is it that makes an entity tax-exempt?”

“As state taxation cases and the congressional effort to answer that question proceed, there will continue to be an interest in charity care and what it means, how much must be provided, and how it is counted,” he added.

**“If reform passes, it will bring the first  
federal tax law change to the  
community benefit standard since 1969.”**

T.J. SULLIVAN, DRINKER BIDDLE & REATH LLP,  
WASHINGTON

Tom Mayo cited the pressure on state and local governments caused by an increased demand for Medicaid and reduced tax revenues because of the recession. “With or without health reform at the national level, tax-exempt hospitals and health systems will be a tempting target for cash-strapped jurisdictions, which these days is just about everyone,” Mayo said. “I expect to see continued work on a charity-care requirement at the federal level. The new Form 990 and Schedule H this year are only the beginning of a strong federal push on governance issues.”

Gerry Griffith predicted increased IRS scrutiny of community benefit with whistleblower activity increasing significantly in the tax area, focused on excess benefit, exemption, and unrelated business income issues.

“State and local tax collectors will increase the pressure on hospital tax exemption, including more challenges to ancillary operations and even to core hospital functions based on levels of quantifiable community benefit provided, while the IRS, using additional compliance checks and audits, will probe further into health care executive compensation,” Griffith said.

Eric Tuckman said changes in uncompensated care will require “community benefit” to be redefined. “New metrics will be developed by regulators and public advocacy groups to determine whether nonprofit organizations are fulfilling their public purpose while access to care and the scope of services and programs offered will be evaluated to determine if public charitable purposes are being met,” he said.

T.J. Sullivan said that, while developments on the national stage both in Congress and at the IRS will keep tax law compliance front and center, exemption under state law also will command significant attention from health lawyers.

“It took Nixon to open China. It took a Republican senator to tighten the standards for hospital tax exemption. If reform passes, it will bring the first federal tax law change to the community benefit standard since 1969. The proposed changes are basic, but I know a camel’s nose when I see one,” Sullivan said.

“The real fear arises when one ponders how the Illinois high court, or else the Legislature, will resolve the state tax exemption issue raised by the Provena Covenant litigation. Exemption will be preserved, but I foresee a third state joining Texas and Pennsylvania with community benefit expenditure standards,” Sullivan said.

“IRS emphasis on executive compensation will continue unabated, and the compensation and community benefit worlds will continue to evolve as the data from the new Form 990s starts to be analyzed,” Sullivan continued. “From an enforcement standpoint, I have never seen the IRS as aggressive on nonprofit executive com-

pensation as they are right now, another response to Senator Grassley’s efforts.”

Michael Peregrine agreed. “The combination of continued pressure on the rebuttable presumption of reasonableness under Section 4958 and the carry over of the executive compensation examination matters referenced in the 2009 IRS Hospitals Report will combine to produce a noticeably more aggressive IRS posture in terms of intermediate sanctions on excess compensation payments,” Peregrine said.

“Simply because Grassley’s amendment on the rebuttable presumption did not find its way into the health reform package (to date) doesn’t mean that the thought behind it—that there have been unintended consequences to its application—is going away,” Peregrine continued. “For that and similar reasons, I foresee state charity officials being particularly aggressive pursuing instances of perceived excess executive compensation, particularly in situations where the IRS is constrained to act because the organization has established the rebuttable presumption.”

Elisabeth Belmont said she, too, expects 2010 to be a year in which health care providers will see developments in the standards and operations for tax-exempt hospitals, particularly in the area of community benefit.

“Regardless of the ultimate content and fate of community benefit legislation and ongoing litigation in the states, one can see a rapid evolution at work, beginning with the Catholic Health Association’s voluntary guidelines for informational uniform community benefit reporting to the mandatory disclosures on Schedule H with mixed information and enforcement goals and, likely soon, some form of quantitative rules for community benefit that will alter the substantive standard under Section 501(c)(3) for health care organizations,” Belmont said.

Peregrine said governance issues also would be a significant focus of the IRS in 2010. “My expectation is that the agency will become more vocal in identifying problematic governance practices that are identified in the course of the examination process,” he said.

“I don’t think they’re training their examination agents on corporate governance issues just to broaden their minds. While IRS is highly unlikely to raise poor governance practices to exemption-level concern, my expectation is that any particularly problematic practices they identify will be brought to the sector’s attention,” he said.

Griffith agreed that good governance will become a more direct tax issue as IRS audits step up scrutiny of governance practices and the agency begins mining data from the new and expanded Form 990 to design future audit and compliance initiatives.

Sullivan also agreed. “Who would have thought the IRS would join the SEC and state attorneys general in cracking the whip for good governance? Nonprofit health care organizations may wince, but I think what has happened—in contrast to what was threatened by the Senate Finance Committee—has been measured and good for nonprofits, including both boards and executives,” Sullivan said.

“This trend is not going to peter out. Increased reporting and disclosure requirements will continue to improve governance, and as best practices evolve and are adopted broadly, the whole sector benefits. We all should keep a keen eye on 2010, Senator Grassley’s last year as ranking member on the Finance Committee, as

## The Health Law Reporter Editorial Advisory Board Looks Beyond 2010

Many board members said uncertainties surrounding health care reform left their crystal balls hazy or even opaque this year, though many doubted reform would address, much less solve, the myriad challenges facing the U.S. health care system.

Kirk Nahra and Vickie Yates Brown said issues left unresolved and necessary adjustments to those addressed in rules and legislation will be a recurring focus. Bob Roth agreed. "If broad reform is not enacted, the debate about it will dominate. If, however, broad reform is enacted, there will be a plethora of spin-off questions, not the least of which will be how the system will provide access to millions of new insureds, who will almost certainly consume more health care services than they did when they were uninsured," Roth said.

Those board members able to see through the haze suggested the following areas could come into play in the next three to five years:

**Biologics and Genomics.** Doug Hastings said that over the next five years potential breakthrough developments in biologics and genomics could create great new treatments but also very complex legal issues related to FDA approvals; patent protection; coding, coverage, and payment; and privacy and security.

**HIT Implementation.** Hastings also cited "connected health," in which traditionally non-health care focused IT and consumer electronics companies seek to develop health care products for consumers, triggering health regulatory, government contracts, and FDA issues. Brown cited issues stemming from enactment of the HITECH Act that, along with the ensuing regulations and guidelines, will significantly expand the privacy and security portion of HIPAA for years to come.

**Globalization.** Fred Entin pointed to the increasing globalization of health care. "Millions of patients across our borders are a market too lucrative to ignore so U.S. providers will continue the trend of the last few years of investing in, affiliating, managing, and establishing operations abroad," he said. "At the same time medical tourism, or the treatment of U.S. patients in settings outside of the United States may accelerate and will certainly be widespread within five years. The next step in the evolution of 'medical tourism' will be the inclusion of an option in health benefit plans to travel abroad for care," he predicted.

**ERISA Reform.** John Blum predicted that health reform will require a re-examination of ERISA and the continued application of the preemption doctrine both for purposes of determining liability for costs of patient care and with respect to initiatives to launch health insurance coverage reforms similar to those undertaken in Massachusetts and San Francisco.

**Medicare Enforcement.** Roth said the Obama administration's regulatory and enforcement priorities for Medicare and other government health insurance programs also will be important to watch over the next three to five years. Sweeping changes to the Medicare program in the health reform bill, coupled with FERA on the federal level and the continued enactment and growing use of state false claims statutes, will cause enforcement to expand significantly in the years ahead, he said.

improved nonprofit governance may be his most cherished legacy," Sullivan concluded.

**8. Health Plan Regulation.** Most advisory board members agreed that health care reform is the driving force behind changes in health plan regulation that are likely to surface in the coming year. In fact, Kirk Nahra said that "to the extent that 'health care reform' turns out to mean 'insurance reform,' this may end up being the biggest issue over the next few years."

Nahra said a key question is whether health care reform will "leave a viable health insurance system." If reform eliminates limitations on coverage for pre-existing conditions or health care underwriting, but does not expand the pool of potential insurers, "how will health insurers (and the employers who foot much of the bill) possibly control their costs?" he asked. Making insurers "the bad guy" in the health reform debate "will undercut one of the key pillars of our current health care system," he added.

Vickie Yates Brown called health plan regulation "one of the most significant issues contained within any of the health care reform legislation," and Toby Singer agreed that "more attempts to regulate health plans" will grow out of health reform measures.

T.J. Sullivan said health plan regulation will follow any health reform legislation, bringing "many newly insured patients to providers, who will be nearly as grate-

ful for an expanded market as will the drug companies."

But whether increased federal regulation of health plans will stimulate competition among plans "remains to be seen," he said. Further consolidation of the market is possible, but Sullivan said he does not foresee more conversions by nonprofits to for-profit insurers. "Today's remaining nonprofit plans are true believers," he said, "and, depending on the public option compromise chosen, their ranks might even increase."

Mark Waxman said changes in plan regulation made as part of health care reform are leading toward provider integration that will bring about an evolution in both plan-provider relationships and provider-provider relationships. "The current view," he said, "is that the system is headed back to a capitated, or modified capitated, approach to plan-provider contracts."

Doug Hastings said health plan regulation will be a major issue for 2010 regardless of the passage of reform legislation. "The challenge will be to match state or federal mandates to expand access with the ability to deliver more cost-effective care. Systems of integrated care that coordinate the payment function with the delivery function . . . appear to have advantages as compared to payers and providers who negotiate in an adversarial manner," he said.

**9. Medical Staff.** Advisory board members said the hottest trend of 2010 in the medical staff arena will be the growing use of hospital-employed physicians. According to Gerry Griffith, the expected growth will come, at least in part, because of hospital acquisitions of physician practices and the formation of integrated networks.

T.J. Sullivan agreed. “Hospital-physician alignment and employment arrangements will continue to grow in a difficult economic and regulatory environment, and while most of the ideas are recycled, hospitals and physicians will try to work together again to protect their incomes,” he said.

Howard Wall said that the “surge in hospital employment of physicians and an abandonment of the independent practice model” by new doctors may increase the odds of success for ideas like clinical integration. He praised the “opportunities for cooperation and collaboration” that are coming out of the health reform movement.

Vickie Yates Brown echoed Wall’s comments, and added that implementation of changes required by the health reform movement could lead to the formation of accountable care organizations to measure quality and/or productivity.

But Doug Ross sounded a cautionary note, saying that an increase in employed physician arrangements could lead to an increase in litigation against hospitals for violating the corporate practice of medicine doctrine. “As hospitals and physicians align more, and given the unsettled nature of this doctrine in many states, expect more attention here,” he said.

Mark Waxman said another area in which hospitals need to tread cautiously is physician discipline. “Behind every attempt to address quality in the medical staff arena lurks a potential whistleblower defense,” he said. “Hospitals and large groups that attempt to push providers to improve their quality and responsiveness face increasing ‘counter-threats’ from physicians who may feel they were subjected to quality challenges because they were concerned about patient quality or allegedly were unaware of inappropriate inducements for referrals.”

“This challenge makes the medical staff disciplinary effort harder than ever,” Waxman said. “Yet, its effectiveness is critical to the improved functioning of the medical staff and the hospital.”

Mark Kadzielski agreed with Waxman that “peer review issues will be fought harder as physicians and others struggle to keep their livelihood.”

**10. Labor and Employment.** Advisory board members also predicted that labor and employment law issues will re-emerge as a hot topic in the coming year. Mark Waxman described this area as “undergoing a rebirth of interest,” while Toby Singer said that, given the new administration, she expects these issues to get even more attention.

Doug Hastings said that traditional labor law issues—such as union-management relations—“will be very important and visible in 2010.” Add in the implications for health care workers in the health reform bills, the high unemployment rate, the trend toward employed physicians, and continued staffing shortages “and you have the elements of a very robust year in health care labor and employment,” he said.

Legal problems brought on by labor shortages in the health care arena are on the minds of several board members. T.J. Sullivan said localized shortages may grow worse as health reform passes, while Doug Ross predicted that shortages could lead to conflicts between nurses and other paraprofessionals.

Two board members, Fred Entin and Howard Wall, commented on the proposed Employee Fair Choice Act (EFCA). Wall said the health reform debate has “moved the card check legislation to the back burner” and that many doubt there are enough votes in the Senate to bring the proposal to the floor.

But Entin said that a number of unions that recently have made inroads into the health care professions “appear to be waiting for the passage of the act before they kick into serious action.” These organizations, along with the nurses’ unions, “are likely to become more active once the details of the EFCA are known,” he said.

Mark Kadzielski added that the “recent consolidation of nursing unions and the aggressive activities of other health workers’ unions will cause further stresses on the health care system in 2010.” He predicted that more issues, like union challenges to mandatory H1N1 vaccinations, will be hard fought.

Waxman said he foresees a rise in wages and hours litigation, as well as in traditional union activities. Providers should review their policies and state and federal rules on joint employment, independent contractors, and related issues, he said.

Elisabeth Belmont added another potentially hot labor and employment issue to the list for 2010: employer liability for postings made by employees on social media sites, such as Facebook, Twitter, and YouTube.

“Although social networking sites can be powerful business tools, they also carry risks, including inadvertently disclosing corporate trade secrets or engaging in behavior that can harm a company’s reputation,” she wrote. “Health care providers need to consider how employee social networking affects their corporate policies on confidentiality, trade secrets, proprietary information, product or service introductions, discrimination, harassment, and other issues.”

Belmont suggested that health care employers warn employees that workplace conduct rules apply online, determine what online activities they should permit or prohibit in the workplace, and consider the extent to which they can impose controls on non-workplace social networking.

**Honorable Mention: Public Health.** Several board members pointed to the H1N1 flu pandemic and its implications for health lawyers, hospitals, and communities as illustrating the increasing importance of public health issues and as a reason to rank this topic in the Top 10.

Elisabeth Belmont said concern over public health preparedness remains high despite some signs that influenza activity may not reach the level some have feared. “Nevertheless, most H1N1 indicators remain higher than normal for this time of year and there is a continuing concern about virus re-assortment that makes emergency preparedness a continuing focus for health care providers in 2010,” Belmont said.

“Researchers in Vietnam have reported a cluster of seven cases of pandemic H1N1 flu that were resistant to the antiviral drug oseltamivir (Tamiflu). This shows that resistant 2009 H1N1 viruses are transmissible and can

replicate and cause illness in healthy people in the absence of selective drug pressure,” she noted.

“Providers in 2010 will continue to wrestle with issues such as protection of employees and maintaining operations, implementation of altered clinical pathways, and public health and provider coordination that need to be addressed at the present time to ensure an adequate level of preparedness,” Belmont continued.

“Because major disasters occur infrequently, health care organizations may be ill-equipped to evaluate major strengths and weaknesses of their programs and should, therefore, implement quality metrics to develop performance measures in emergency management,” she said.

“Hospitals should also be encouraged to study the times when their emergency departments experience extreme volume and demand for services, which are commonly ignored as outlier periods,” she added.

According to Belmont, the Trust for America’s Health and the Robert Wood Johnson Foundation have said the economic crisis is jeopardizing the nation’s ability to handle public-health emergencies and possible bioterrorist attacks. “In addition, federal and state governments that are under financial duress are cutting programs that help communities respond to disease outbreaks, natural disasters, and bioterrorism incidents, which could negatively affect future preparedness measures.”

“There is a significant risk that health care providers who fail to take adequate preparedness steps, even in the midst of the current economic crisis may be held liable,” she said, adding, “As Judge Learned Hand noted in *The T.J. Hooper*, 60 F.2d 737 (2d Cir. 1932), ‘There are precautions so imperative that even their universal disregard will not excuse their omission.’”

Howard Wall, agreed, noting that the Institute of Medicine “has declared that the nation’s system of emergency care is in crisis and is less able to withstand a major natural—Hurricane Katrina—or manmade—911—disaster than it was in 2001.” In addition, the Center for Studying Health System Change has reported that the shortage of specialists to provide call coverage in the nation’s emergency departments threatens not only patients’ access to high quality emergency care in local communities, but also adverse patient outcomes, he said.

Doug Ross said public health could be a health law “wild card” in 2010. “I foresee the possibility of investigations, litigation, and legislative response to a variety of issues arising from HHS missteps concerning the H1N1 vaccine, Ross said. “However, if the flu never becomes the calamity some fear (Y2K anyone?) then we all may skate on this one,” he added.

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

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