Lead Report

Outlook 2008

Health Care Quality, Fraud and Abuse Top List of Health Law Issues for 2008

Patient care quality, which affects all sectors of the health industry and is a focal point for setting reimbursement and assessing compliance, will be the top health law issue in 2008, according to an informal survey of members of *BNA's Health Law Reporter's* editorial advisory board.

Advisory board members, asked to rank the key issues for health care providers in the coming year, said quality of care issues will edge out fraud and abuse, which ranked first in *HLR*'s 2007 Top 10 survey, because quality concerns drive so much of the debate over how to improve, and finance, the nation's health care delivery system.

For 2008, health information technology and taxation place third and fourth, while health care reform—energized by the upcoming elections but occurring primarily in the states—places fifth. Medicare, antitrust, labor and employment, governance, and medical staff issues round out the rest of the Top 10 list.

Several other issues—including alternative dispute resolution, public health, and transactions and financing—received honorable mention while board members glimpsing into their crystal balls said retail medicine, medical tourism, and e-discovery will raise important health law issues in coming years.

Following are the issues board members ranked highest among their concerns for 2008.

1. Health Care Quality. "Quality, quality, and quality," both William A. Dombi and Howard T. Wall III said when asked for their rankings.

"All health care sectors are affected by the growing movement to focus on quality relative to service performance, reimbursement methodology, accountability, and compliance enforcement. Whether it is future health policy efforts or current corporate accountability, quality is the driving issue for 2008," Dombi said. He is with the Center for Health Care Law, National Association for Home Care, in Washington.

Wall, with Capella Healthcare Inc. in Nashville, Tenn., said "the Office of Inspector General, Joint Commission, Department of Justice, and Centers for Medicare and Medicaid Services . . . they are all in on the act."

According to Douglas A. Hastings, with Epstein Becker & Green PC in Washington, quality is the "health care issue of the decade."

The focus on quality creates "an opportunity for the best performers in the industry to create a profound transformation and then to open up best practices through transparency of data and collaborate to spread positive change," Hastings said.

Health Law Reporter's Top 10 for 2008

Advisory board members ranked these the most important health law issues for 2008:

1. **Health care quality,** spurring change throughout the health care industry, takes the top spot.
2. A close second, **fraud and abuse** enforcement from multiple directions commands attorney attention.
3. **Health information technology,** while promising to improve quality and lower costs, poses challenging legal questions.
4. Continuing pressure on exempt health care organizations keeps **taxation** hot.
5. **Health care reform** moves onto the list with election year proposals and system-wide challenges.
6. The **Medicare** program continues to have wide-ranging legal ramifications.
7. Increased enforcement of **antitrust** laws, both by government and private litigators, is predicted.
8. Continued pressure by unions and work force challenges keep **labor and employment** issues in the forefront.
9. **Corporate governance** initiatives challenge the fortitude and competencies of board members faced with new oversight responsibilities.
10. Changes in physician/hospital relationships brought about by economics and regulatory proposals keep **medical staff** issues on attorneys' radar screens.

Thomas W. Mayo called quality a "hydra-headed" issue. "Besides the usual stuff about how to measure quality, we have pay for performance (P4P), the transparency of quality information and ratings, patient safety/medical errors, electronic medical records and other IT matters, and Medicare and Medicaid reimbursement issues; the list just goes on and on," he said. Mayo, of counsel to the firm of Haynes and Boone LLP in Dallas, also teaches internal medicine at a University of Texas medical school and law at the Southern Methodist University Dedman School of Law.

Robert L. Roth, with Crowell & Moring LLP in Washington, said 2007 may have been the turning point in the quality debate as both public and private payers increasingly committed to the "paymentization and compliancization" of quality.

W. Reece Hirsch, with Sonnenschein Nath & Rosenthal LLP in San Francisco, agreed, citing CMS's recently issued report to Congress on value-based purchasing, the OIG's move toward enforcement consequences for poor-quality care, and the fact that the plat-

form of every presidential candidate speaks to health care quality in some way.

Wall in Tennessee and Elisabeth Belmont of MaineHealth in Portland, Me., said quality of care and patient safety failures, once the turf of state regulators, are targets of fraud investigations by both DOJ and the OIG.

Not only does the OIG have "quality of care on its 2008 Work Plan but Inspector General [Daniel R.] Levinson announced that it is at the top of the OIG's enforcement priorities," Belmont said. Levinson has said that the OIG will expand its efforts to enforce quality of care in residential treatment facilities, psychiatric centers, facilities that treat people with development disabilities, and hospices, she said.

Other board members said that, while some federal initiatives are under way, they see most of the action occurring in the states. Mark A. Kadzielski, with Fulbright & Jaworski LLP in Los Angeles, said "At least 10 states in the past several years have adopted laws mandating the reporting of medical errors and are actively gathering data on the National Quality Forum's 'Never Events,' paving the way for similar reforms in other states in 2008."

Of course, the downside of mandatory error reporting is increased regulatory oversight and potential media scrutiny, Kadzielski said, "but so far, health facilities seem to have weathered that storm." Some are becoming more transparent about disclosing errors to patients, families, and, when appropriate, the public, he added.

Activities at the state level "stand in sharp contrast to the inept handling of the federal regulatory process under the Patient Safety and Quality Improvement Act of 2005," he continued. "No draft regulations for this important federal quality law have been issued some 30 months after President Bush hailed this legislation as a major part of health care quality reform," he said.

Kadzielski said progress is impeded in part because resources are inadequate at most health care regulatory agencies on both the federal and state levels, "while programs designed to fine providers for quality errors, or to cut reimbursement for poor quality providers under the rubric of 'value purchasing' are just coming onto the regulatory scene.

"2008 will be a very interesting time to watch how the government increasingly levies financial penalties against health care providers in more areas than ever before. Healthcare facilities especially have to fight back against these penalties, whatever their amounts, or run the risk of being seen as easy targets for regulators to hit repeatedly," Kadzielski added.

According to Crowell & Moring's Roth, tying payment to quality "may, at last, cause all of the talking to give way to action.

"For the past forever, including last year, I identified quality of care as an issue where there was much handwringing but little action. The Medicare FY 2008 Inpatient Prospective Payment System Final Rule may have changed this by identifying certain 'never events' for which hospitals will not get paid despite having to provide additional services," Roth said.

"If public and private payers can successfully fashion payment solutions for their quality concerns, the changes in the quality arena are likely to be significant as quality is transformed into a routine payment and compliance issue," he added.

Stephanie W. Kanwit, special counsel to America's Health Insurance Plans in Washington but speaking for herself, focused on the tie-in between quality and health IT. Advances in care quality "are premised on providing more and more relevant information to consumers, as well as on fostering the adoption of more effective treatments," she said. This includes payment incentives to physicians and other providers to recognize and reward quality performance and reduce the overuse of inappropriate or unnecessary services.

Currently, some one-third of primary care physicians with health plan contracts have quality incentives in those contracts, Kanwit said. In addition, the Medicaid program as well as private health plans are testing and adopting P4P initiatives and Medicare has done demonstration programs, she said.

"Everybody's talking about quality, but we have to watch carefully to see who is doing something."

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

Meanwhile, key stakeholders—including consumer groups, health plans, and more than 135 physician associations—are collaborating to promote a uniform strategy to measure and report provider performance, she added.

Hirsch, however, had a comment on P4P programs that no other board member made. "It is a bit disingenuous" to term the federal P4P an incentive program when CMS "essentially deducts from dollars that hospitals already have earned for services provided." As a result, he said, CMS proposals to base Medicare hospital payments on quality measures will continue to generate controversy.

Kanwit said a correlative to P4P is how to get consumers current and objective information on which health care services provide the best value. A big issue is the need for an independent entity to set priorities for research to compare the effectiveness of new and existing drugs, devices, procedures, and therapies and distribute the results in a useful form to patients and clinicians, she told BNA.

Quality of care and the transparency of information about that care go hand in hand, she said. "Promoting quality improvement has to be grounded on the concept of an 'informed consumer.' There's truly a ground swell, both public and private, for greater transparency," Kanwit said.

Fredric J. Entin, of Foley & Lardner LLP, Chicago, said quality now is widely recognized as a health system board fiduciary responsibility.

Boards of directors have been put on notice to make immediate and serious efforts to understand their hospital's ability to monitor and provide quality care, Entin said, citing *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors*, the September 2007 joint report by the OIG and the American Health Lawyers Association (AHLA).

"Those providers that fare well will not only have better control of the way in which patients are cared for but, increasingly, outcomes will be measured. On the commercial insurance front, more payers will be imple-

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menting P4P-based contracts that will evolve from input- to outcomes-based payment," Entin said.

Hirsch noted the links between quality and health IT, observing that employers are beginning to sponsor personal health records (PHRs) for employees as well as disease management programs to help manage the cost of health benefits.

While the information maintained in PHRs could make an employer's disease management program more effective, proposing to use it for this purpose will create inevitable tension in the area of medical privacy, he said. "How can the employer obtain access to that information without offending privacy laws or the privacy expectations of employees?" he asked.

T.J. Sullivan, with Drinker Biddle & Reath LLP in Washington, had the last word. "Medical errors and hospital-borne infections have simply got to be reduced. Where the requisite pressure will come, however, remains to be seen. Price shopping by patients may remain a pipe dream, but outcomes measures and infection rates could easily drive consumer decisions," he said.

"Everybody's talking about quality, but we have to watch carefully to see who is doing something," he added.

2. Fraud and Abuse. Board members ranked fraud and abuse at or near the top of their concerns because they expect 2008 to see increased administrative, regulatory, investigative, and prosecution activity. According to Kirk J. Nahra, of Wiley Rein LLP, Washington, "The fight against health care fraud rages on.

"While, once upon a time, there was the possibility that health care fraud would be a 'flavor of the month' to be put aside when the next hot topic came up, it is clear that the fight against health care fraud is here to stay. The government is putting more resources into this fight, and has more expertise on health care fraud issues, than ever before," he said.

The need to comply with the latest round of Stark law regulations, the OIG's use of enforcement to advance the quality agenda, and DOJ's use of deferred prosecution agreements (DPAs) to monitor medical device companies accused of taking kickbacks as some of the reasons board members said they expect an active year in federal enforcement.

With CMS expanding its use of demonstration project authority to empower recovery audit contractors and program safeguard contractors with bounty rewards for uncovering fraud and abuse, the industry should expect an active year in federal enforcement, they said.

Several board members observed that the presentment requirement of the False Claims Act is headed to the Supreme Court in *Allison Engine Co. v. Sanders*. Presenting the question whether the FCA applies to subcontractors or just to the entity actually presenting a claim to the government, *Allison Engine* is not a health care case but "looks like a blockbuster with some real effect on the health care industry riding on the outcome," according to Richard Raskin, with Sidley Austin in Chicago.

Sanford V. Teplitzky, with Ober Kaler in Baltimore, agreed, pointing out that there has been "no letup in the number of qui tam cases filed" and reports by Justice and the OIG confirm that health care investigative and enforcement priorities are, in large measure, driven by these cases.

Expanding the FCA to downstream contractors could mean more valuable government and private industry resources will be diverted to responding to cases that "in the majority of situations amount to unsubstantiated rumors and allegations containing incomplete and often inaccurate facts," he said.

States' enactment of false claims legislation as required by the Deficit Reduction Act (DRA) will only exacerbate this situation and significantly increase the time, effort, and money health care companies that conduct business in more than one state will have to expend in responding to allegations of health care fraud or abuse, Teplitzky added.

Jack A. Rovner, with Neal, Gerber & Eisenberg LLP in Chicago, said he also expects increased government investigation and enforcement of fraud and abuse laws generally and FCA activity in particular.

"Political pressure, especially in an election year, coupled with the 2006 Medicare Part D reconciliation process, which was delayed but should be well under way in early 2008, should spur intensified 'investigations' of 'overpayments' to Medicare private plans and Medicare providers, of improper Medicare private plan marketing—especially through agents and brokers, and enrollment improprieties," he warned.

"The fight against health fraud rages on. The government is putting more resources into this fight, and has more expertise on health care fraud issues, than ever before."

KIRK NAHRA, WILEY REIN LLP, WASHINGTON

Eric Tuckman, with Advisory Health Management Group, Manhattan Beach, Calif., said he sees 2008 bringing "more novel and aggressive uses of fraud and abuse laws to improve patient care quality.

"Use of the FCA will continue in cases of marginal quality or the provision of unnecessary services, but identifying these cases more often will occur from sophisticated data mining techniques able to reveal heretofore unknown trends or patterns of practice," Tuckman predicted.

Hirsch said he expects the OIG to continue to refine its new theories of liability relating to quality of care. For example, he said, the OIG/AHLA *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors* "clearly highlighted that liability for failure of care or medically unnecessary care may be imposed upon organizations that neglect appropriate supervision and oversight of clinical services.

According to Roth, another factor motivating the aggressive use of the fraud laws is that the government "continues to be enamored by the quick policy-changing results that can be achieved through enforcement actions." In his comments, Roth renewed last year's criticism that regulatory agencies are allowing government enforcers to displace regulatory guidance

and agency decisionmaking with criminal and highly punitive FCA civil actions.

The result, he said, is that providers and payers have developed a siege mentality, while the government's obligation to exercise thoughtful restraint in exercising its great power continues to wane. This can be seen, for example, in the penalties for failing to comply with the FCA education requirement in the DRA, Roth said. These are "Draconian and include debarment, nonpayment of claims, treble damages, penalties and, in some cases, attorneys' fees and costs."

Nahra expressed similar concerns. "There is a real risk that the government's expertise—and willingness to be aggressive and push the envelope—is creating a situation where, in many situations, there isn't a fair fight." Government tactics are very aggressive and sometimes, as in the KPMG case, they get shot down, he said.

"But even in those situations, it is long after the fact, meaning that companies and individuals have already gone through the wringer," Nahra said. "The result is that the government increasingly is using its aggressiveness and market clout to push a result that it otherwise would not be able to get," he added.

"The government should focus its attention on the many situations where there is real bad behavior, rather than simply using its clout to get more money in borderline situations, Nahra said.

In Raskin's opinion, increased fraud enforcement will stem, in part, from the fact that "2008 is an election year and no elected official or prosecutor wants to be seen as soft on fraud. The issue cuts across political parties and, better yet, enforcement pays for itself . . . and more." The pharmaceutical and device sectors are likely to be hardest hit, he predicted.

Tuckman said he sees fraud and abuse statutes being "interpreted in such a way as to challenge utilization practices relative to Medicare patients when lengths of stay are reduced below community standards or when P4P programs are misused and go beyond quality considerations."

Also of concern to some board members is the government's use of deferred prosecution agreements or nonprosecution agreements under which companies are required to retain monitors who are paid by the companies, but who report directly to the government.

"To the extent that certification of OIG compliance agreements can be viewed as 'corporate integrity agreements light,' these agreements, which are in addition to CIAs, should be viewed as 'CIAs on steroids,' " Teplitzky said. Under these agreements, monitors are involved in the company's everyday operations and even must approve every consultant relationship, the attorney said. The health care industry "should not be surprised to see the use of deferred prosecution agreements expand to other areas," he said.

What concerns Katherine Benesch, with Duane Morris LLP in Princeton, N.J., is that use of DPA monitors and overseers "has removed the management of health care organizations from experienced providers." One hopeful sign, she said, is that four members of Congress, including Rep. Bill Pascrell (D-N.J.), are asking for House Judiciary oversight over DOJ's use of DPAs and monitors, and for legislative controls over how the monitors get picked and paid, which—according to Teplitzky—is handsomely. It has been reported that former U.S. Attorney General John Ashcroft's law firm could earn as much at $52.2 million serving as a monitor in a case against a medical device company, he said.

Similar concerns are triggered by the Recovery Audit Contractor (RAC) Program created by the Tax Relief and Healthcare Act of 2006, which uses these third parties to uncover fraud and overpayments in federal health care programs.

"Medicare is experimenting with a wide variety of time- and cost-efficient compliance enforcement measures to pick off the low hanging fruit among allegedly abusive health care providers," Dombi said. "From expanded use of demonstration project authority to empowering RACs and program safeguard contractors with bounty rewards, 2008 promises to be an active year," he said.

According to Teplitzky, industry terms these activities "RAC attacks." Early results—RAC personnel identified more than $303.5 million as improper payments in the first 18 months of the program, according to the government—have encouraged CMS to expand the program nationwide during 2008, well ahead of the 2010 date mandated by Congress, he said.

The continued expansion of hospital ownership by physicians . . . likely will engender a closer look at the long-standing rationale for the whole hospital exemption."

ERIC TUCKMAN, ADVISORY HEALTH MANAGEMENT GROUP, MANHATTAN BEACH, CALIF.

With payment tied to a percentage of recoveries, "early RAC reports have included significant and substantial recovery demands. Under the program, payments to the RACs are based upon the initial recovery demand, not upon the actual repayments, if any, following appeals. In fact, a number of providers have successfully appealed the initial RAC recovery amounts," he said.

"More recently, CMS has announced a number of limitations on the activities of RACs which hopefully will reduce the angst and turmoil caused by these entities, but only time will tell," Teplitzky said.

Changes to the Stark law in the Stark II Phase III regulations published in September generated numerous comments, but Sullivan said that while Stark arguably has been the number one issue since 1988 or 1989, "now the emperor has new shoes." With the introduction of an expanded "stand in the shoes" doctrine for relationships involving physician practice members, hospitals and integrated delivery systems are being forced to reevaluate many of their long-standing arrangements with physicians, he said.

Belmont said she sees the goal of the Phase III regulations—both proposed and effective—and the host of proposed changes to the Stark regulations in the 2008 Medicare Physician Fee Schedule as being to "dramatically limit physicians' financial relationships with other health care providers."

Entin said this could result in significant disruption to existing physician/hospital relationships as what had been understood to be legal and mutually beneficial is

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revised. Hirsch said that in California the stand-in-the-shoes doctrine has caused medical foundations to restructure the form, if not the substance, of professional services agreements with affiliated medical groups.

The new rules have "left many issues unanswered and raised significant new questions," Teplitzky said. Of perhaps greatest importance is the damage the regulations could do to academic medical centers around the country, he said. "CMS issued a one-year delay on the application of the regs to AMCs, but the issues remain to be resolved," he told BNA.

Hirsch said the effective date delay itself is "actually quite limited in scope." It does not apply "where a nonprofit hospital is contracting with a physician group and the entities are not both affiliated in the same health care system . . . or to contracts between an academic hospital and a physician group that is not part of the AMC." As a result, he said, the stand-in-the-shoes rule still will lead to the restructuring of many common hospital-physician relationships.

Another problem that remains to be tackled is the blurring of the line between Stark and Medicare/Medicaid reimbursement represented by the 2008 Medicare Physician Fee Schedule regulations, board members said.

"The fee schedule's 'anti-markup' rules for diagnostic tests that are purchased or performed at a site other than the office of the billing physician have created as much consternation, confusion, and controversy as any rules in recent memory," Teplitzky said.

"CMS 's final rule would also have significantly altered the 'same building' test for ancillary designated health services performed by a physician group," he added. "If it had been left standing, this would have required many physician group practices to institute substantial changes—including perhaps finding new and larger office space—to avoid serious, yet unintended, violations of the Stark rules."

"Although CMS just announced that the new anti-markup provisions, except for anatomical pathology services performed in a centralized building, have been deferred until January 2009, CMS is not finished with this issue," he said.

The *Federal Register* notice says that during the delay they will potentially issue clarifying guidance and new proposed rules, he said, adding "this issue is far from over."

Tuckman said he foresees possible changes to the Stark law's whole hospital exemption. "The continued expansion of hospital ownership by physicians, both with regard to specialty hospitals and well as general acute care facilities, likely will engender a closer look at the long-standing rationale for the whole hospital exemption," he predicted.

The news for providers on the enforcement front is not all bad, however, Teplitzky said. Industry consideration of the OIG's voluntary disclosure program should increase during the coming year with beneficial consequences, Teplitzky said.

"Results continue to demonstrate the benefit of that program under certain limited circumstances," he said. "Specifically, a majority of the filings under that program have been referred by the OIG to the Medicare fiscal intermediaries and carriers and durable medical equipment carriers for a simple overpayment recovery. Of the cases that remain, a small minority were settled with the imposition of a CIA," he said.

3. Health Information Technology. Health information technology ranked high on board members' lists because of its promise and challenges. While it promises to help improve quality and reduce costs in the long term, short-term challenges relating to fraud, tax, and financing—all in the face of feasibility and technological hurdles—abound, they said.

To Howard Burde, with Blank Rome LLP in Philadelphia, health IT is the answer to reducing health care costs. "The only way to increase insurance levels is to reduce duplicative utilization by sharing information." Short of cutting provider reimbursement, there are no real alternatives, he said.

According to Hirsch, the Department of Health and Human Services clearly is on board. Its willingness to use the Medicare program's leverage is seen in developments such as the recently introduced bipartisan legislation to spur physician adoption of e-prescribing technology and the HHS initiative to incentivize physicians to adopt HIT systems with additional Medicare reimbursement, he said.

"HHS has the ability to use both carrots and sticks to move forward the cause of health care IT in 2008," Hirsch said.

But Wiley Rein's Nahra warned that developing health information technology "presents an enormous challenge." Nahra co-chairs a federal advisory work group preparing recommendations for the American Health Information Community on how the government can best support interoperable electronic health information exchange while protecting personal health information.

"The HIT marketplace is proceeding far faster than the ability of the regulatory system to keep pace," he told BNA. There are extremely complicated regulatory challenges and the difficulty of resolving them threatens to delay realistic progress, he said.

Belmont said 2008 will be a time of emerging uses of health information beyond traditional treatment and payment activities. Health information will be used for P4P programs, to achieve transparency that helps consumers make decisions about price and quality; for provider profiling; and for quality and utilization review programs. It also will be used in business analytics to test existing constructs for uses and disclosures of health information under privacy and security and intellectual property laws as well as contractual relationships among providers, payers, and other parties, she said.

These secondary uses of health data will require resolution of issues related to access, use, and control and ongoing monitoring by involved stakeholders, particularly at the local level, Belmont continued. Furthermore, evolving issues such as health record banking, implementation of regional health information organizations (RHIOs) for the exchange of health information, and the growing use of personal health records (PHRs) continue to keep the electronic health record (EHR) landscape in flux, she said.

There is "lots of talk" about how good EHR and a national health information infrastructure will be for the country, Rovner said, "but little help on how to pay for it; how to get the industry stakeholders to cooperate, rather than war, over its implementation; and, perhaps most vexing, how to find a viable economic model to pay for the investment to develop it."

Rovner said he sees the economic failures of several initiatives, such as RHIOs, as underscoring the struggle to find a viable economic structure to justify the necessary investment. Furthermore, he said, continuing disputes among health care stakeholders, including payers, hospitals, physicians, other providers, employer group health plan sponsors, government, and consumer privacy advocates, "over who owns and who controls electronic health records will, as with the economic changes, continue to forestall effective development of interoperable EHRs."

J. Mark Waxman, with Foley & Lardner LLP in Boston, expressed similar concerns about the potential financial consequences of HIT development. "With interest rates at a low level over the past several years, and managed care rates climbing, the overall environment has been strong. But if interest rates begin to rise, and pressures to spend on capital for IT remain strong while keeping prices fairly stagnant, will we see hospital margins erode, or weaker systems disappear?" he asked.

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W. Reece Hirsch, Sonnenschein Nath & Rosenthal, San Francisco

In any case, failing to act quickly enough to develop a regulatory framework could mean the marketplace develops without appropriate controls, Nahra said. "Much like the need to test Medicare alternatives, we need to find a realistic means of encouraging swift development and adoption of HIT, while at the same time developing a realistic regulatory structure, even if it is not a perfect regulatory structure," Nahra said.

HIT advances "are absolutely critical to promote both quality and efficiency of operations, as health plans work with physicians and other health care providers to spread the use of both EHRs and PHRs," according to AHIP's Kanwit.

Kanwit said PHRs are truly "the wave of the future" and will have "an enormous positive impact on costs and quality throughout the system by preventing errors and adverse drug interactions." AHIP has worked with the Blue Cross and Blue Shield Association to develop a model health plan PHR and operating rules that make the PHRs portable, so consumers who change health plans can take them with them, she told BNA.

"E-prescribing is also a key initiative," Kanwit said, as health plans and pharmacy benefit managers work to develop tools to help physicians prescribe electronically, including allowing checking of patient histories and information about generic alternatives to be provided.

But these health plan IT initiatives work well only when they are truly interoperable, which HHS defines as the ability to communicate and exchange data accurately, securely, and effectively with other IT systems, she said. "In other words, they can't operate in silos," with hospitals and other providers unable to share data.

"It's the classic VHS/Beta problem," Nahra said, referring to the videotape recording war between two rival incompatible formats in the 1970s and '80s. "If we had the ability to say today that we are going to create VHS instead of Betamax so everybody should buy VHS then everyone could buy the same system. But it doesn't exist right now. So doctors and hospitals are deciding that they need electronic medical record (EMR) systems for their own operations and are not yet worried about sharing that information. They can't wait for that capability."

Kanwit indicated the scope of the problem, saying studies show "only about a quarter of physicians use some form of EMRs, with fewer than that using what would be called a 'fully operational' system that would allow collection of patient information electronically, online ordering of lab tests, and electronic display of test results."

A lot of this is because many physicians do not want to spend a lot of money today "when they may buy a Betamax" that will have only a brief shelf life and quickly be replaced by the competition, Nahra said. "But there is no solution to this dilemma today; it's just out there."

Despite the "Beta problem," Burde said that "virtually every major acquisition by a health care provider or payer, or by state or federal programs involves health IT." In fact, he said, the largest procurement in health care in the coming year will be the joint DOD/VA EMR system. "The standards used for that acquisition will affect the entire health care industry," Burde said.

The DOD/VA acquisition "is a big deal because they are at least going to link among the VA hospitals," Nahra said.

Board members generally were pessimistic about achieving HIT interoperability anytime soon. Rovner, for example, predicted that we will "continue to hear lots of talk, but not a lot of meaningful action." Still, he said, "the incentives will continue and activity will be high."

Entin agreed, but said "the fragmented nature of health care IT will continue to be a roadblock to the implementation of technology solutions beyond the four walls of a single hospital or system."

One perhaps unwelcome result, Rovner predicted, is that said's appetite to enforce privacy, security and transactions rules under the Health Insurance Portability and Accountability Act will grow along with the rise of electronic health information and its accompanying privacy and data security concerns.

Hirsch agreed, saying that, "although there have been no public announcements regarding the OIG's security audit of Piedmont Hospital in Atlanta in the spring of 2007, 2008 is likely to see some degree of stepped-up HIPAA security enforcement." CMS has contracted with PricewaterhouseCoopers to conduct covered entity security audits, and the OIG reportedly plans to conduct at least two more, he told BNA.

4. Taxation. Tax considerations, especially those affecting exempt health care organizations, again make this issue a Top 10 concern for health lawyers in 2008, board members said. As Tom Mayo put it, "Nonprofit health care will continue to be under the microscope in 2008."

Wall agreed. "As long as Chuck Grassley is in the Senate there will be hearings that put tax-exempt providers under the microscope. The government will continue to require more reporting of data to establish

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proof of community benefits to justify avoiding the tax man," Wall said.

In addition, "the state and local revocation of tax exemption, emerging corporate governance principles, congressional scrutiny and legislation on hospital billing and collection practices will continue to transform the face of traditional community tax exempt hospitals," he added.

John J. Durso, with Ungaretti & Harris in Chicago, concurred, predicting that "the never-ending battle" challenging the tax-exempt status of providers will continue" both at the federal level, with executive compensation questions, the new Form 990, and Government Accountability Office investigations, and at the state level, with attorney general investigations and property tax challenges.

Tuckman said that, "while 2008 may not bring a national standard regarding quantitative requirements for charity care and community benefits, it is quite likely we will see further legislative and regulatory action in the states to mandate a definition of these components and set specific levels for compliance."

Although there are "bona fide industry arguments relating to the elements that should be included in any computation of charity or community benefits, establishing minimal standards will constitute clear and simple compliance guideposts and enable regulators and the public to determine which institutions are applying the revised standards effectively," Tuckman said.

Tuckman also said he expects private litigation to change from challenging overall institutional policies relative to billing and charity care to attacking the actual implementation of these policies. The increase in the number of uninsured "as well as a significant increase in the number of under-insured individuals makes it certain" that there will be more private and class action lawsuits in this area, he predicted.

"Finally, we may see regulators shift their focus from individual community benefit and charity care determinations to investigating whether exempt entities are utilizing their overall assets for the benefit of the community," he said. "The existence and maintenance of large positive balance sheets may also trigger governmental review of whether the public is receiving maximal beneficial use of these exempt assets," he added.

According to Michael W. Peregrine, with McDermott, Will & Emery LLP in Chicago, "the role of the federal government in the oversight of nonprofit health care facilities will continue to evolve with the ongoing interest of the Senate Finance Committee and the continued reconsideration of the community benefit standard—and its 'community board' component—for determining tax exemption eligibility.

"We also can expect to see continued focus on executive compensation, from both the IRS—with the expectation of additional formal reports from the IRS and its analysis of the data from the community benefit compliance checks of 2006—and state charity officials, who can be expected to be aggressive in terms of their review of potentially problematic compensation arrangements," Peregrine added.

Sullivan said tax issues remain high on his Top 10 list this year "if only for the sheer volume of developments percolating through Congress, the IRS, and state and local authorities.

"Last year, providers no sooner got over the shock of Illinois Attorney General Lisa Madigan's ill-fated proposal to require tax-exempt hospitals to provide 8 percent charity care when the minority staff of the Senate Finance Committee issued a Discussion Draft featuring the proposal that all tax-exempt hospitals should be required to provide free care up to a certain income level *and* should be required to provide charity care accounting for no less than 5 percent of their revenues or expenses," Sullivan said.

"While neither of these proposals is likely to become law as is, the continuing legal battles over property tax exemption at Carle Foundation and Provena Covenant Medical Center in Illinois ultimately may force a legislative solution there," Sullivan continued. "Once Pandora's Box is opened, the hospital community cannot be certain of a perfect outcome.

"While this may be the worst of times for legislation, it is the best of times for exempt hospitals to strengthen their charity care and community benefit records," he said, adding "It's all going public soon.

"The new IRS Form 990 and Schedule H will finally bring about comparable national reporting for all nonprofit hospitals' charity care and community benefit records. With the Form 990 already routinely available on the Web, the expanded content and specificity means the amount of sunshine and opportunity for outside scrutiny has never been higher," Sullivan said.

"All the new emphasis on measuring and reporting charity care and community benefit occurs against the backdrop of continuing governmental and public scrutiny of executive compensation, benefits, and governance practices throughout the nonprofit sector. Hospitals ignore these tax issue—and the need to tell their story in the most positive way possible—at their own peril," he said.

Belmont agreed, saying that, while Forms 990 "have long been subject to public disclosure, they have become increasingly important as a comprehensive report on the activities and operations of tax-exempt health care organizations, including both financial and nonfinancial matters.

"Because the redesigned Form 990 probes much deeper into hospital operations and community benefit practices, and because it requires more information on the core form with respect to the compensation of officers, directors, and key employees, health law practitioners likely will have greater involvement in the review of those compensation arrangements," Belmont said.

5. Health Care Reform. The last serious attempt at national health care reform was more than a decade ago, but board members asked to rank the key issues for health care providers in the coming year think the time has come for another round.

While few said they expect significant reform at the federal level prior to 2009, many said they expect the dialogue spurred by the upcoming elections and state initiatives to make health care reform a significant feature of the health care legal landscape for 2008.

"Everybody knows the health care system is broken," Mayo said. "The uninsured and under-insured and what to do about them will no doubt be fueled by the presidential race," he said, adding, "the media are all over this issue and will keep it in front of us throughout 2008."

According to Hastings, "When health policy is hot, health law issues follow, both in the form of legislative and regulatory actions and in the form of transactions and new arrangements structured to capitalize on business opportunities created by policy actions. The inevitable changes will mean more work for lawyers."

Being in the middle of a presidential election cycle means that at the federal level we will "only see the trailers for real reform, not the movie," Burde predicted. Kadzielski was equally pessimistic, citing the "debacle" over the State Children's Health Insurance Program and saying the funding crises on meaningful health care reform legislation in Congress is a major problem.

"Whether anyone on the federal level will have the courage to take action on these health care issues in an election year is highly doubtful. Yet it is critical that action occur," Kadzielski said.

While payers and providers are watching the national debate, they are responding to market opportunities and changes on a state-by-state basis, Burde said. The only real health care reform is taking place in the states, with "interesting approaches being implemented in Tennessee, Georgia, and Florida," Burde said.

Mayo agreed, predicting that in the absence of any meaningful action from Congress, the states will continue to improvise.

"When health policy is hot, health law issues follow, both in the form of legislative and regulatory actions . . . and new arrangements structured to capitalize on business opportunities."

DOUGLAS HASTINGS, EPSTEIN BECKER & GREEN PC, WASHINGTON

Mark Waxman also concurred, saying that, while the election—and the health reform platforms of the candidates—is the No. 1 story for 2008, it will be notable "as much for the conversation it produces as for the resulting gridlock on any meaningful legislation along the way."

Waxman predicted that "one hot topic will be whether Massachusetts-style health reform can be successful even in Massachusetts where the financial challenges are now becoming evident."

Raskin was more hopeful. While it may be 2009 before specific federal legislation is proposed, health care companies and providers would do well to keep a close eye on the national political debate reinvigorated by the Massachusetts insurance experiment and presidential campaign proposals. "Health care reform is back on the agenda," he said.

Rovner said he sees a half dozen key issues that could and should be addressed as part of a broad reform initiative, including measures to address the problem posed by the un- and under-insured, the cost of Medicare and Medicaid, quality and pay-for-performance issues, and health IT and a national health information infrastructure.

"It is not clear that any of these will get done by the new administration and new Congress, but there will be lots of talk, debate, ideas, concepts, promises and attacks until the election," he said.

Roth said he sees only inaction. Health care reform will be the "top fizzle issue in 2008," he said.

"There seems to be absolutely no momentum towards comprehensive health reform at the federal level. This stems from several factors, including the highly partisan mood in Congress, the jockeying of the two major parties on health care for the 2008 election, the efforts being made at the state level to try to address the problem of the uninsured, and the perceived lack of coherent voter disapproval focusing on any particular issue," Roth said.

As a result, Roth said, state experimentation will continue to shape the debate while smaller changes command significant attention. An example of the latter is all the attention being paid to the Medicare sustainable growth rate formula used for physician payment rates, he said.

"No doubt something will get done, but only after significant discussion" as the parties seem more focused on finding wedge issues for the campaign rather than on achieving bipartisan policy goals, Roth said. "The slim Democrat majority in the Senate prevents any significant partisan action and bipartisan action does not look likely," he added.

Any reform will need to deal with the employer's role in health insurance, several attorneys said. "On the one hand, you have states, like Massachusetts, that are forcing employers to be more involved," Nahra said. "On the other, constant cost pressures are creating real economic tensions for even the biggest employers, witness, for example, the auto industry where health care costs are deal-breakers with the unions. This seems to be a system facing chaos. Moreover, there are real legal issues about employers' ability to control costs through employee behavior.

"Employers are interested in wellness programs that encourage better employee behavior, but there are real legal restrictions, including privacy laws, that put pressure on the idea of the 'one size fits all' employer-sponsored coverage, where all employees, within the range of choices, pay the same price." Charging employees with problem behavior higher premiums might reduce costs, but will trigger a debate on whether this is appropriate, he said.

"I think costs and legal land mines will lead to real pressure to permit employers to be more active in this area as one way to help preserve an employer-sponsored system that seems on the verge of collapse," Nahra said.

Jack Rovner had similar concerns. "There is a lot of enthusiasm for 'forced' wellness initiatives by employers," he said. The 2007 HIPAA wellness program rules, for example, which take effect this year, allow health insurers and employers to provide real financial incentives to encourage and reward healthy behavior, he said. "But how will these programs be reconciled with Americans with Disabilities Act requirements (at least as the Equal Employment Opportunity Commission seems to interpret them) that appear to conflict with the wellness rules? How will these programs be managed to avoid HIPAA Privacy Rule violations when employers may want hard data to show whether the programs are working, including who in the company is using them

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and who in the company may need 'encouragement' to use them?"

In picking health care reform as a key issue, Mayo said that employers "seem finally to understand this is their issue, too. The middle class also eventually will figure out that their insurance coverage isn't nearly as good as they thought it was. Sooner or later, these forces will converge and this will be the 'perfect storm' issue well into the next decade."

Wall was willing to predict a few consequences. "Despite all of the lofty policy discussions in Washington about safety, consumer choice and expanded coverage," what all of the industry groups who lobby Congress will push for is funding, he said.

"Managed care plans will fight to preserve the huge gains that they have made during the Bush Administration while physicians will fight to avoid further cuts in payments. Adequate funding for traditional Medicare and Medicaid will continue to be the top issue that will cause the phone in the typical congressional office to ring off the hook," Wall continued.

"Look for a Republican administration to expand some of the concepts that came along with Medicare Part D, which should favor managed care and big drug companies," he said. "If the Democrats take office, expect a larger share of the nation's GNP to go into health care spending, which should benefit providers," he said.

6. Medicare. Medicare, according to board members, retains its spot on the Top 10 because it will continue to be a central component of the health care delivery system with ramifications—whether related to reimbursement, fraud prevention, or quality and technology innovation—across the board.

Mayo summed it up: "It's so big, and it's so large a part of the debate about health reform, and there's so much going on—between absorbing the changes wrought by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), Part D, or changes in reimbursement policies—that Medicare will continue to be a central feature of the health law industry."

Roth agreed. "Medicare is simply too vast and important. The big question is whether Congress will change the funding level for Part C, Medicare Advantage, and whether these programs will continue to be embraced by beneficiaries, providers, and private payers, and will actually reduce the growth rate for Medicare costs," he said.

Nahra cited the importance of Medicare because of its dominant financing role . "There are pressure points everywhere—Medicare, Medicaid, private employer-sponsored insurance, individual coverage, etc. I put Medicare at the top of the list, mainly because it is the biggest chunk of that issue," he said.

"We are in constant exploration of whether there are new models to make this system work. In addition, there continues to be a systemic tension between encouraging reasonable alternatives and providing so many restrictions to these alternatives that they are not likely to be sufficiently useful," he said.

He acknowledged that there are fraud risks associated with some of these alternatives, but said that there is "a real possibility that these experiments will fail simply because the regulatory requirements—on issues that clearly matter less than the potential fraud—will get in the way of achieving effective results."

He said it is difficult to look at the Medicare system as it now stands and have anything other than substantial concern about its future. "Developing an effective means of testing realistic alternatives—with appropriate but not undue regulatory requirements—will be a key challenge in the years ahead," he said.

Hirsch said Medicare's importance also stems in part from the leverage it affords in forcing change and innovation.

According to Benesch, "Medicare and Medicaid are 'hot-button' issues for several reasons. First, all of the fraud laws relate back to Medicare and Medicaid as the basis of many problems. Second is the problem of cost and the uninsured."

Federal reimbursement policies "create incentives that determine who gets what care, and who can and cannot afford treatment," she said. "While policymakers wrestle with how to pay for medical care, more and more of the population goes without. Thus, the results of these debates are of paramount importance in terms of the effectiveness of our health care system to care for those who need it the most," she said.

Kanwit said Medicare is important because of its successes. "The Part D drug program is working well, giving beneficiaries a choice of plans, including prescription drug plans (PDPs) and Medicare Advantage plans with drug coverage, and many offer enhanced benefits, including coverage in the gap, low premiums, and zero or reduced deductibles," she said.

"One Medicare issue of importance to health plans participating in Medicare Advantage and Part D involves the scope of federal preemption under Section 1395w-26(b)(3) of the Medicare Act, 42 U.S.C. § 1395w-21 through 28, as amended by the MMA," Kanwit continued.

"Currently on appeal to the U.S. Court of Appeals for the 11th Circuit in *Dial v. HealthSpring of Alabama Inc.* is the question whether the MMA is a 'complete preemption' statute, thus affording federal jurisdiction over removed claims that otherwise would arise under state law. In the case, health plans claim the statute offers both complete preemption and 'ordinary preemption'—preempting state laws governing areas the MMA reserved to the federal government," she said.

Dombi cited developments with Medicare Advantage during 2008, whose growth will change as reimbursement level are threatened with further reductions. "This will lead to changes in health care provider business with shifts in network relationships and potentially expanded traditional fee-for-service Medicare," he said.

Belmont said she is anticipating a new CMS clinical trials policy on when and under what circumstances Medicare will reimburse for associated routine costs. Belmont said this policy could clarify when research is, and is not, covered.

"CMS will likely try to resolve some of these issues in 2008, perhaps in the form of rulemaking. Because research is becoming more and more commonplace in hospital settings, the compliance issues surrounding the policy, whatever it may turn out to be, will be significant for all who work with hospitals or clinical trial sponsors," Belmont said.

Sullivan said the sleeper issue is "whether Congress will again pick up the issue of specialty hospitals and try to determine, in lieu of free market forces, who will

be the winners and who will be the losers in the potential growth of physician owned single specialty hospitals, a movement opposed by acute care general hospitals."

7. Antitrust. Board members ranking antitrust a top issue for health care lawyers cited increasing private litigation and stepped-up federal enforcement as issues that will keep competition concerns in the forefront in 2008.

Toby G. Singer, with Jones Day in Washington, said antitrust will stay hot because the Federal Trade Commission's decision in *Evanston Northwestern Healthcare*, finding a hospital merger violated federal antitrust laws, has reinvigorated antitrust enforcement with respect to both hospital and health plan mergers. Private plaintiffs have discovered health care as well, litigating everything from exclusion from health plan networks to nurse wage-collusion cases," she added.

Hastings agreed antitrust enforcement is up. "After *Evanston*, hospital mergers are being scrutinized more closely again, with second requests stemming from premerger notification requirements on the increase," he said. "Constant consolidation on the one hand and expansion into new markets on the other creates antitrust issues that will make headlines," he said.

Entin said that, while the outcome of the FTC challenge to the Evanston Northwestern Healthcare merger "was widely anticipated" in light of the FTC decision not to require divestiture, it is unclear whether success in the case will further embolden the agency.

"Was this just an academic victory or can the industry expect more challenges post-merger?" he asked.

Sullivan thinks it can. Antitrust enforcement, which was "always one of the big three until the 1990s, appears to be on the upswing," at least at the FTC, he said, adding that the commission's retrospective review of the Evanston Northwestern merger and its compromise outcome likely signal an era of increased activism on hospital consolidation.

"Although the antitrust laws also were invoked as part of the scrutiny of group purchasing organizations earlier in the decade, recent activity appears to have shifted to a consumer protection focus while the antitrust aspect has quieted," he said.

Citing the cyclical nature of hospital merger and acquisitions, Tuckman predicted that, as financial performance recedes, it is inevitable 2008 will see more hospital transactional activity.

"These transactions have gotten and will get increased scrutiny from antitrust enforcement officials using nontraditional means of assessing the anticompetitive impact, increasing the likelihood of contested challenges," Tuckman said.

Rovner said the *Evanston* decision "appears to mark the return of aggressive government antitrust enforcement in health care and signals an analytical shift from earlier unsuccessful government enforcement actions involving hospital mergers."

This new analytical approach, which moves away from relying on patient discharge data and instead uses data on managed care organization contracting "appears realistically to capture the nature of to whom providers sell their services and focuses provider competition on their 'real' customers—the insurers that pay for most of the services they sell," Rovner said.

"Look also to DOJ interest in health plan mergers as provider political opposition to payer consolidation builds pressure for government action," he added.

Raskin said "critical antitrust issues facing health care companies in 2008 will include disputes between acute care and specialty hospitals, 'bundling' of products and services, authorized generics, health plan mergers, hospital mergers, and physician networks."

Kanwit said she expected some big pharmaceutical-related antitrust developments. "First, the MMA requires brand name drug manufacturers to file certain agreements with the FTC, including settlement agreements between generic drug companies and brand names that pay compensation to the generic patent challenger in return for refraining from launching the generic product for a period of time," she said.

The commission has been very negative on these "reverse payment" settlements and their implications for drug costs, she said.

"Second, the FTC is also coming out with an authorized generics study which should be interesting, given the prevalence of generics in the market," she said.

8. Labor and Employment. Labor and employment issues will continue to preoccupy health care providers in 2008 as workforce shortages and union initiatives put added pressure on hospital operations and bottom lines, board members said.

According to Hastings, "the slowing of the economy, more and more employed physicians, continued staffing shortages and other workforce issues, and increased union activities at hospitals all add up to a robust year in health care labor and employment law."

Sullivan agreed there is "little evidence to suggest that recent activism by labor unions will slow any time in the near future. There is too much at stake." Hospitals employ huge work forces, Sullivan continued, and represent big opportunities for unions. "With labor shortages at least in the nursing area, that means continued pressure for these employers," he said.

Dombi added that "skilled health care staff remain in short supply while health care unions such as the Service Employees International Union are gaining strength in numbers and political power." This year, he predicted, "unionization efforts and the collective bargaining strategies will trigger a new era in health care affecting health care businesses and involving both federal and state legislatures."

Kadzielski also cited the unionization of health care employees as a major challenge for providers. "Unions have figured out that American businesses can 'outsource' many different types of jobs to overseas companies, except those in the labor-intense health care sector," he said.

"This is a very high-stakes endeavor for both unions and hospitals, with a winner-take-all outcome in literally every circumstance," he said.

"In 2008, the next shoe—corporate campaigns—will drop more frequently," Kadzielski added. Through these initiatives, unions will continue to hit health care institutions in the pocketbook, spending significant resources to challenge hospital plans for development, new buildings, etc.," he said.

Durso agreed that providers will continue to grapple with unions seeking to organize workers, noting they have been active in exposing alleged uninsured billing inequities and, in some communities, are leading the

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challenge to the tax-exempt status of the nonprofit providers whose workers they are trying to organize.

Wall said the looming shortage of health care workers goes beyond the much discussed nursing shortage.

"An overlooked developing story is the crisis that many communities will face when the physicians in their 50s and 60s begin to retire. Many hospitals, especially those in small rural communities, are finding it impossible to recruit specialists such as cardiologists and orthopedic surgeons," he said.

In addition, "increased enforcement of immigration laws is making it more difficult to recruit foreign born physicians," he said. "With medical school entering classes not expanding, who is going to take care of the baby boomers who will be retiring in record numbers over the next 20 years?"

9. Governance. Governance issues arising from quality, fraud, and tax concerns that will increasingly be brought to the board room for review also will be a central focus for health care attorneys in 2008, *HLR* board members said. For members of boards of health care institutions, "the plate keeps getting more full," Entin said.

"Whether as a result of the OIG's challenge to nonprofit boards to monitor and understand quality, the IRS's focus on financial transparency to satisfy their communities that they are deserving of the benefits of tax exemption, or because Sarbanes-Oxley issues remain a core board responsibility, compliance with a broad portfolio of rules unique to health care continues to be squarely on boards' agendas," he said.

Because of these rules, boards will need to examine existing structures and charters to determine whether they are capable of handling their ever-expanding agenda, Entin added.

Belmont said boards are being told to increase their scrutiny of quality and compliance and that they will need to a determine whether they have processes in place to effectively monitor these key concerns.

According to Entin, this means that individual False Claims Act liability now is a risk for board members, high-ranking officers, and legal counsel for health care organizations. "Boards, along with their legal counsel, must ensure that proper oversight occurs and that they make immediate and serious efforts to understand their hospital's ability to monitor and provide quality care," he said.

John D. Blum, with Loyola University School of Law Institute for Health Law in Chicago, predicted that the OIG's new focus on quality issues in governance combined with related issues of patient safety and ongoing matters concerning community benefit "will place increasing pressure on the board in its trustee and fiduciary roles."

Even the IRS is climbing aboard the "corporate governance bandwagon," Sullivan said, noting that, while most of the IRS's activities will be limited to education about best practices and sunshine, there still is room for improvement of actual practices in many health care organizations.

"IRS activity and finance committee scrutiny is just one more indication that, no matter from what perspective health care organizations are viewed, good governance can protect against a lot of ills, while governance weaknesses can be very destructive," he said.

Peregrine commented that the new IRS's new Form 990 places corporate governance of tax-exempt organizations front and center. "The attention paid to corporate governance issues is consistent with the agency's overall efforts respecting corporate governance initiated in 2007 with the release of draft governance guidelines," he said.

The importance of the initiative was underscored in the public comments of IRS Commissioner Steven Miller that promoted governance as a new "pillar" of the IRS' compliance and education activity for the tax-exempt sector, Peregrine said.

"The governance-related provisions incorporated within the redesigned Form 990 include those relating to board size and structure, conflicts of interest management, director independence, intra-board relationships, audit committee practice, written governance policies, and the role of governance in the preparation and review of the form," he said.

For members of boards of health care institutions, "the plate keeps getting more full."

FREDRIC J. ENTIN, FOLEY & LARDNER LLP, CHICAGO

In addition, Peregrine said, "while increasing attention will be placed on the board's obligation to oversee quality of care, the standards applicable to such oversight will remain fluid for the foreseeable future as both providers and regulators work to balance the benefits of such oversight—including government's related role—with the risk that such oversight could create a new and unnecessary burden on the board."

Peregrine also said he expects that state charity officials, the IRS, and the courts "will increasingly look to the Panel on the Nonprofit Sector's Principles of Self Regulation as de facto 'best practices' for nonprofit organization governance." He predicted that, "whether by resolution of corporate controversies, new bar association/policy group publications, or through avenues, there will be a continued focus on the role of the general counsel and increased access to the governing board."

Raskin agreed, saying health care systems and companies will continue to face governance pressures. "In particular," he said, "public companies can expect continued SEC scrutiny of options practices as well as review of international operations under the Foreign Corrupt Practices Act," he said.

10. Medical Staff. Medical staff issues, too, will keep health care law practitioners busy throughout 2008, according to *HLR* advisory board members.

Sullivan said that peer review, credentialing, contracting, call coverage, and physician/hospital alignment issues will continue to be hot.

Waxman said he believes legal issues concerning hospital-physician relationships will move to the forefront. He specifically said that doctors and hospitals are exploring different model relationship structures, with the result that employed physicians and practice acquisitions are "making a fairly strong comeback."

Hastings said that "changes in the way health care is delivered due to population demographics, technology,

The *Health Law Reporter* Editorial Advisory Board Looks Beyond 2008

Gazing into their crystal balls, several *HLR* advisory board members took a stab at predicting issues that will be facing health care law practitioners within the next several years.

Retail Clinics. As health care costs continue to rise, look for retail health clinics to proliferate, Elisabeth Belmont said. Embraced by large retail merchants such as Wal-Mart, CVS, Target, and RiteAid, and major health systems such as Aurora Health, Geisinger, and Sutter Health, they are growing in popularity with consumers because they have low overhead; provide convenient, affordable basic care in short visits; have transparent pricing; and provide for effective communication, she said. Various compliance and risk management issues "come with this territory," Belmont said. In particular, she said, regulation of retail clinics, whether under new or existing laws, will keep health lawyers busy.

Howard Wall also cited the rise of retail health clinics. "The offer of cheap flu shots and free generic drugs is drawing consumers into chain-operated clinics and drug stores that will also be able to provide annual sports physicals for kids and other services families need at a fraction of the time and cost of traditional medical care."

Medical Tourism. Patients unable to find affordable quality care in the United States increasingly will go abroad. In some cases, the treatments they seek are unavailable in the United States because they have not been approved; in others, the cost of the procedure is simply prohibitive here.

Howard Burde said U.S.-educated doctors increasingly will treat American patients in nearby islands and South America. He added, however, that medical tourism also is inbound. "With the rise of wealthy classes in countries with health care systems less well-developed than ours, individuals are seeking care in the United States in increasing numbers," he said. American hospitals are actively pursuing these patients, while businesses are forming to facilitate these opportunities, Burde said.

Jack Rovner predicted medical tourism could "explode" in the next four to five years. He foresees U.S. citizens obtaining elective heath care oversees covered by U.S. insurers.

"The economics and the emergence of quality 'Western-style' facilities in the United Arab Emirates, India, Southeast Asia and elsewhere may . . . make going oversees an attractive option for 'luxury' care at much lower cost than in the U.S.," he said.

Fred Entin agreed. "Millions of uninsured and under-insured patients, large and small employers, and third-party payors will consider care abroad as they look for affordable non-emergency procedures and treatments, some of which are not even available in the United States," he said.

Entin predicted globalized health care will raise questions of professional liability, privacy, licensure, benefit plan design, taxation, insurance regulation, accreditation, and quality. Additionally, he said, many U.S.-based providers are forming alliances with and investing in overseas operations. The growing opportunity American health care providers have to deliver care to citizens from all over the world will encourage many others to broaden the definition of the communities they serve, he said. He added that, while many kinds of health care require local services, "increasingly, many diagnostic procedures can be done remotely from any place in the world."

E-Discovery. Litigation-related issues were on the minds of several board members, with Richard Raskin and John Blum both foreseeing complex discovery issues. With the development of electronic health records, management of discovery—especially e-discovery—will gain in importance, they said. Managing "e-discovery can become all-consuming," Raskin said.

Belmont also sounded a warning, saying e-discovery "creates new opportunities for disclosure of information not anticipated by both providers and patients." Unlike in other industries, health care records are often in the possession of independent physicians, labs, pharmacies, hospitals and payers, making records administration and e-discovery requirements much more challenging, she said.

Belmont also cautioned that hospitals need to be careful in responding to requests from private insurers for information about treatments received by their insureds and, more generally, about the hospital's policies and protocols because their responses may be discoverable in a subsequent malpractice action. She said she anticipates this type of activity will become "more mainstream."

Belmont also is concerned about discovery of metadata, or hidden tags inserted in electronic documents. Metadata, allows litigants to trace changes in the documents and identify the person who made or edited each entry, she said.

It also can lead to problems maintaining privilege. "Responses to e-discovery requests need to be carefully controlled so that databases of privileged peer review and quality assurance data are not inadvertently disclosed; metadata can show, for example, exactly who has access to the peer review databases and plaintiff's counsel can use this information in order to argue that the requirements of the privilege were not satisfied," she noted.

Internet 'Care.' Howard Burde expects Internet-related legal issues to arise in light of the growing proliferation of health care Web sites. He noted that Google and Microsoft are continuing to develop such sites. "Consumer response will tell us whether Americans are ready to treat their health care and health care information like other kinds of information," he said. He also predicted that the incentive to use the Internet to explore health issues "will rise with the cost of health care."

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and other factors is causing a radical shift in the locations and economics of health care delivery. Hospitals and physicians, who used to have independent relationships governed by historical medical staff rules, now are required to collaborate to a much greater extent to meet evolving care protocols and quality standards, yet at the same time are acting more and more as competitors in the increasingly outpatient-based delivery environment."

Wall said that both the "rise of specialty hospitals and other physician-owned entities that compete with hospitals and increasing physician resistance to following EMTALA on-call requirements will continue to be trigger points in the rift between hospitals and their staffs."

However, by far the most talked about "hot" medical staff issue for 2008 is the Joint Commission's revision of Medical Staff Standard 1.20. So controversial has it been that the version of MS 1.20 scheduled to take effect July 1, 2009, is actually the third attempt in four years to finalize the standard.

The current version draws the most criticism on two points: (1) its mandate that certain requirements be included in the medical staff bylaws and (2) provisions that allow the medical staff to bypass the medical executive committee (MEC) and take issues directly to the hospital's governing body.

Benesch said that, while the medical staff arena is one health care issue that has not had a lot of activity, that is likely to change in light of MS 1.20, which is "poised to create new animosities between the medical staff organization, its executive committee, and the hospital, and a lot of work for medical staff leaders, hospital administrators and medical staff attorneys."

Benesch also challenged the Joint Commission's assertion that the provisions will improve the quality of care. In fact, they will have the opposite effect, she asserted.

"It will be interesting to see whether or not the Joint Commission comes to its senses and revises this rule," Benesch said. Given the overwhelmingly negative industry reaction to the current draft, it "is hard to believe" that the standard will take effect in its current form, she added.

Kadzielski said the "adoption of new standard MS 1.20 has sent hospitals into a tizzy. In effect, by mandating wholesale bylaw changes to conform to new MS 1.20 by mid-2009, the Joint Commission has antagonized health care providers unnecessarily."

Amending medical staff bylaws is very complicated, usually requires a supermajority vote, and can take anywhere from six months to two years to complete, he said. Furthermore, amending staff bylaws could require corresponding amendments to the hospital governing body's bylaws, he added.

The provision that allows the medical staff to bypass the MEC and go directly to the governing board also is particularly troublesome, Kadzielski said. Although Joint Commission officers have stated the provision should get little use, Kadzielski said that the fact it exists at all will prompt more and more medical staff members to use it. This, in turn, will lead to confusion as the board must decide whom to listen to—the medical staff or the MEC. It comes down to "damned if you do, damned if you don't" for the board when it is forced to take sides, he added.

The process, moreover, defeats the whole purpose of having a medical executive committee, which is elected by the medical staff to represent it before the board, he pointed out. Although some have suggested that the provision is needed to curtail board-controlled MECs, Kadzielski said that he has never seen one. He also noted that most medical staff bylaws already spell out a process for removing members of the MEC who the staff believes are not representing their interests.

Overall, he said, the new provisions are confusing. While he is hoping for clarification from the Joint Commission, Kadzielski called the idea that the Joint Commission will return to the October 2006 version "a nonstarter." The Joint Commission simply will not scrap two years of work, he said.

Nevertheless, he observed, the controversy "comes at a time when the Joint Commission senior leadership is being replaced. What the new leadership team will do to respond to this and other pressing issues will certainly be an important health care development in 2008."

Hirsch said he is hopeful the commission will reconsider Standard MS 1.20 so that extensive revisions to many organizations' medical staff bylaws will not be required.

The Joint Commission's revised MS 1.20 is "poised to create new animosities between the medical staff organization, its executive committee, and the hospital, and a lot of work for medical staff leaders, hospital administrators and medical staff attorneys."

KATHERINE BENESCH, DUANE, MORRIS LLP, PRINCETON, N.J.

Although compliance is not required until July 2009, if the standard is not modified medical staffs will probably need to begin the amendment process in 2008, given the lead time typically needed to secure medical staff approval to incorporate new substantive categories and related processes into bylaws, he said.

Wall added that the Joint Commission's actions "will put hospital administrators and medical staff leaders on a collision course in 2008." Revised MS 1.20, in particular, "seems to further emphasize the autonomy of the medical staff, weaken the traditional role of the MEC, and add confusion over shared responsibility in an organization in which the hospital board of trustees is ultimately responsible," he said.

Wall also foresees difficulties with meeting the Joint Commission's Jan. 1, 2009, implementation date for the revised Leadership Chapter, which "requires better communication over quality of care and patient safety, and requires organizations to manage conflicts effectively."

He sounded a positive note, however, saying, "I for one hope that the necessity of addressing the Joint Commission standards will create a forum to allow a dialogue between hospital administration, board lead-

ers, and physicians that will lead to a better understanding of each others' position and create opportunities to address the overriding issue of providing safe, quality health care in a hospital setting."

Blum said he sees the MS 1.20 debate continuing but, like Wall, is optimistic the new provisions will facilitate an era of dialogue and cooperation between medical staffs and hospital governing bodies. In short, he said, this may be what is needed to prompt the two entities to work together to improve quality.

Blum acknowledged that many fear the new standards will add fuel to the ongoing tensions between medical staffs and hospitals over turf by empowering medical staffs to be more aggressive.

But rather than lead to more divisiveness, revised MS 1.20 may instead prompt "bridge-building," Blum said. It could compel hospital boards to be more sensitive to the needs of the medical staff and to be more conciliatory and inclusive when addressing internal issues, he said.

Honorable Mention: Alternative Dispute Resolution. Kanwit predicts the overhaul of the entire medical liability system. Noting that "medical practice is still driven to some extent by fear of litigation" with the result that "dollars are wasted on defensive medicine" and a liability system that doesn't serve the needs of either patients or providers, Kanwit said it is "likely there will be some changes to the system soon."

She highlighted a few changes that have been suggested, including taking medical malpractice cases out of the judicial system and creating special "health care courts" or a dispute resolution process with independent third-party review designed to provide fair compensation for injuries and quick resolution of claims.

Benesch added that the idea of utilizing alternative dispute resolution in medical malpractice disputes is not new. Insurers, however, are unlikely to support wide use of such programs, she said. But ADR is on the rise in just about every other aspect of health care, Benesch said.

It is common today to find claims that arise out of practice group breakups and physician employment going to arbitration, she said. Arbitration is very big in managed care also, she said, and mandatory ADR clauses can be found in contracts between device/drug makers and research organizations that conduct clinical trials. In these areas, she said, more disputes are going to arbitration than to court.

Honorable Mention: Transactions and Financing. Wall said he expects finance and transactional developments to be areas to watch in 2008. "Wall Street is reeling and the credit markets are very tight. The impact of this is likely to linger into 2008," he said.

Roth agreed. "It is always important to follow how capital markets view the health care system," he said.

According to Wall, "With the credit market now much more limited, major tax-exempt financings at facilities with less than premium ratings may get put on the shelf. This may force capital-starved stand-alone facilities to consider selling or joint venturing with for-profit partners," he said.

Private equity firms also may find it harder to finance "go private" deals, so strategies like one-time dividends and stock buybacks used to finance facility and system expansion may continue as companies struggle to bring value to shareholders. "When the public markets again turn to health care, as the markets have always done over the past 30 years, a strong group of old and new faces will be ready to meet the demand of the public investors, Wall said.

Honorable Mention: Public Health. Blum was one of several board members who cited ongoing public health issues and concerns as meriting continued attention by health lawyers in 2008.

"Attention spans may be short but there are still many post-Katrina issues out there along with MRSA infections, flu season, obesity etc. All have legal implications," Blum said.

Wall cited a declaration by the Institute of Medicine that the nation's system of emergency care is in crisis and is less able to withstand a major natural or man-made disaster than it was in 2001.

"From legitimate government efforts such as preparing the nation for pandemic flu on one extreme, to overreaching, governmental intrusions in the rights of individuals and businesses like the New York ban on trans fats or state-wide or community-wide smoking bans in private buildings and outdoor spaces, public health issues will continue to be a focus of lawmakers and regulators, Wall said.

Honorable Mention: Biotechnology. Benesch and other board members predicted that biotechnology-related issues will come to dominate health care law. Advances in biotechnology will "change the paradigm of medical practice," she said.

John Blum agreed, saying that issues concerning stem cell research will continue to arise through 2008 and beyond.

Benesch said biotechnology will affect all areas, from quality analysis to medical records. Moreover, she said, as the practice of medicine becomes more highly specialized scientifically, some adjudications may become difficult for traditional courts.

On the other hand, advances in biotechnology may eliminate some political/bioethical issues, Benesch said. She cited stem cell research in particular. Now that scientists have announced that they can produce stem cells without harvesting them from human embryos, the ethical/political/legal issues surrounding them may go away, she said.

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