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Outlook 2009

Health Care Reform Top Health Law Issue As Economy, New Leadership Drive Change

The economy and its effect on national politics will dictate the health law landscape in the coming year, according to *BNA's Health Law Reporter* advisory board members.

Asked to rank the Top 10 issues facing health care providers over the coming year, board members overwhelmingly selected health care reform as the top health law issue for 2009, followed by fraud and abuse and taxation issues. Said one member: ''The Top 10 will be driven by one issue, the state of the economy.''

Yet in the implosion of the U.S. financial system and the election of Barack Obama, several board members said they see the best opportunity for meaningful health care reform in many years. The majority of board members raised reform from fifth-ranked last year to the top of the pack. As John D. Blum of Loyola University Institute for Health Law in Chicago put it, ''the political stars are aligned and the needs are profound.''

But the nation's financial condition will make reform as difficult as it is necessary, board members also said. Mark A. Kadzielski with Fulbright & Jaworski LLP in Los Angeles said he believes the chance of meaningful health care reform in the next 24 months is ''a 50/50 proposition at best. The economic crises are only several of the deterrent forces Health and Human Services Secretary nominee Tom Daschle and his team face,'' Kadzielski said, citing the intense lobbying expected from major health care interest groups.

According to Howard T. Wall III, with Capella Healthcare Inc. in Franklin, Tenn., cutbacks in funding to providers could not come at a worse time. He said he sees the ripple effects of the economic collapse being felt in the health care sector for years as tighter credit markets squeeze capital spending and merger and acquisition activity, and high unemployment swells already record-high bad debts and the ranks of the uninsured.

John J. Durso of Ungaretti & Harris in Chicago was similarly pessimistic, explaining that the lack of access to capital, by driving the cost of borrowing money higher, will hit hospitals at the same time their investments have lost substantial value, forcing them to merge, affiliate, or sell. ''At the same time, federal, state, and local government is questioning and trying to cut back on reimbursement and tax exemptions, further exacerbating the hospitals' financial difficulties,'' he said.

Gerald M. Griffith of Jones Day in Chicago predicted the bankruptcy of hospitals in urban and rural areas due to cuts in Medicaid funding and increasing charity care demands hitting at the same time due to the credit crisis.

As a result of these pressures, and even though reforming the health care system and covering the 46 million uninsured is a top priority of the incoming administration, few said they expect 2009 to bring major change. This assessment led several board members to count health reform among their topics to watch over the next three to five years.

Reforming a system as large and complex as the U.S. health care system implicates, if not subsumes, fully half the topics rated in *Health Law Reporter*'s 2008 Top 10 survey—the previously top-ranked quality of care as well as taxation, antitrust, Medicare/Medicaid, and health information technology, advisers said.

J. Mark Waxman, of Foley & Lardner in Boston, said a major reform, including universal access to care, cost reductions, and quality enhancement, ''could be the Top 10 topics all by itself.'' Thus, even in the best of times, these board members said, legislators would find effecting reform a daunting task.

As Kirk Nahra of Wiley Rein LLP in Washington explained, reform ''isn't a single legal issue, it is a package'' each part of which will need some support from affected constituencies. Integrating and resolving all these interlocking elements could be an overwhelming

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Health Law Reporter's Top 10 for 2009

Advisory board members ranked these the most important health law issues for 2009:

1. **Health care reform** takes the top spot, driven by a new administration and nearly unprecedented financial conditions.
2. Enforcement of **fraud and abuse** laws continues and expands into new areas.
3. **Taxation** issues involving exempt health care organizations keep tax practitioners busy at both state and federal levels.
4. Complex issues continue to thwart implementation of **health information technology**.
5. **Quality** concerns and issues continue to permeate all levels of health care.
6. **Medical staff** issues continue to arise in a challenging economic and compliance environment.
7. A new administration is poised to keep **antitrust** enforcement up in the face of provider consolidation pressures.
8. **Medicare** continues to be primary agent of change across all issues.
9. Renewed pressure on passage of the Employee Free Choice Act keeps **labor and employment** front and center.
10. **Corporate governance** remains important as boards are required to monitor everything from false claims and competition to quality and compensation.

task, Nahra said. Whether in 2009 or 2010, ''it will dominate the discussion, and the imagination of the health bar and its clients,'' Waxman added.

Conflicts of interest among stakeholders seeking to build coalitions and break resistance will be profound and will force President Obama to decide whether ''the greater risk to the economy comes from enacting, or failing to enact,'' major change, Robert L. Roth with Crowell & Moring LLP in Washington told BNA. As Jack A. Rovner of Neal, Gerber & Eisenberg LLP in Chicago sees the problem, the question is whether the economic meltdown will ''sabotage or stimulate'' reform.

If a large enough percentage of middle-class people lose their health insurance along with their jobs, the resulting political pressures could make fixing the system imperative, Rovner said. But the global economic crisis also could drain so many resources for a recovery that little is left to pay for health care delivery and even less for reform, he warned.

Roth portrayed the opposing positions. ''Some will argue that the difficulty in the economy presents the perfect time to address the long-standing drag that our exorbitant health care costs have had on our competitiveness'' and argue that health care reform is ''central to our ability to keep the economy on track over the long haul.'' Opponents, almost assuredly the majority, he said, ''will argue that we need to get the economy moving before any significant health care reform efforts should even be discussed.'' Roth said his bet is on them.

''My suspicion is that health care reform will be put on the back burner until the economy shows signs of turning the corner. Also, given that significant health care legislation typically occurs in odd-numbered years—the Balanced Budget Act of 1997, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the Deficit Reduction Act of 2005—if health care reform legislation is not enacted in 2009, it will probably be off the table until 2011 and a major election issue in 2010,'' Roth told BNA. But Thomas Wm. Mayo at Southern Methodist University Dedman School of Law in Dallas said that he thinks the Obama administration ''will move on reform in the first year, maybe even the first six months, unless something completely unforeseen happens.''

Daschle, who is Obama's pick to lead the Department of Health and Human Services, ''appears to believe that the Clinton administration's fatal mistake, or one of them, was waiting until the second year to roll out their reform proposal. There are so many moving parts, it's hard to believe they will have a detailed plan that soon, but Daschle personally has a good grasp,'' Mayo added.

Nahra said he doubts dramatic reform will occur in 2009. But he said he does expect to see significant incremental change on particular issues as part of a broader reform movement. He predicted health care organizations and their legal advisers will spend the first part of the year lobbying to effect this change, and the remainder of the year and beyond dealing with its effects.

Board members clearly expect 2009 to be an especially challenging year for health lawyers dealing with legal issues facing all segments of the health care system. The economic crisis and the pressures it exerts on policy makers and regulator should be on every reader's mind in reviewing board members' following rankings of the Top 10 health law issues for 2009.

1. Health Care Reform. Health care reform not only is the most significant health law issue for 2009 but also the one that will ''overwhelm all the others'' as the country struggles to find the most efficient way to accomplish sustainable reform, Stephanie W. Kanwit of America's Health Insurance Plans in Washington told BNA.

T.J. Sullivan with Drinker Biddle & Reath LLP in Washington said that given the amounts at stake and the unpopularity in Congress and the provider community of some of the actions taken in the Bush administration, he would ''not be surprised to see early and sustained legislative and regulatory changes in parts of the Medicare program reflecting 180 degree different priorities.''

''The Top 10 will be driven by one issue, the state of the economy.''

JOHN J. DURSO, UNGARETTI & HARRIS, CHICAGO

Most board members agreed that Medicaid and Medicare reimbursement mechanisms are the driving forces behind the current health care payment system, with the result that any reform must focus on them. ''As the federal government cuts back on its share of Medicaid reimbursement to the states, the states cut back on health care benefits, and the number of uninsured continues to rise. Medicare and Medicaid have become fo-

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cal points in the health care system contributing to the recession. Major insurance reform is needed, and this must start with the Medicare and Medicaid programs, as these are the centerpiece around which most other health care payment issues revolve,'' Katherine Benesch of Duane Morris LLP in Princeton, N.J., said.

She also addressed provider regulation, however. While many different types of regulation are crucial to the functioning, or nonfunctioning, of the health care system, Benesch told BNA, none is more important today than the unfunded mandates in the Emergency Medical Treatment and Labor Act that require hospitals to review and stabilize emergent patients before they can be transferred to an appropriate facility for care.

Kadzielski also addressed the issue of provider regulation. ''Vigorous enforcement of state regulations, with increased enforcement of federal regulations like those under EMTALA that are already on the books, should be expected in a general environment where more governmental regulation and intervention appears to be more widely desired by society,'' Kadzielski told BNA.

Richard Raskin with Sidley Austin LLP in Chicago said health plans in particular should keep a close watch on developments in both Washington and in state capitals because plan regulation will be at the center of any significant health care reform proposals. And, of course, ''the behemoth of all health plans is Medicare,'' he said.

In health plan regulation for 2009, ''Expect big ideas, big plans, and big battles over whether to implement them,'' Raskin said. Wall said he expects ''increased federal spending on health care over the next four years with a larger share of the nation's GDP going into health care spending to the benefit of providers.''

Roth predicted ''a sharp focus'' on Medicare Advantage and prescription drug plan compliance matters and audits and the implementation of enhanced risk adjustment for MA plans. ''This will the beginning of years of disputes in connection with the calculation of plan rates,'' he said. Wall said he also expects Congress, where both Senate Finance Committee Chairman Max Baucus (D-Mont.) and House Ways and Means Health Subcommittee Chairman Pete Stark (D-Calif.) both are on record as supporting such a move, to reduce payments to MA managed care plans to the level of Medicare fee-for-service providers. Roth also sees the government requiring implementation of mental health and substance abuse parity.

Looking at the broader picture, Kanwit described prominent members of Congress like Baucus and Sen. Edward M. Kennedy (D-Mass.) as being ''well along on health care proposals that advocate a comprehensive system overhaul,'' possibly including universal coverage mandates, employer ''pay or play'' requirements, premium subsidies, insurance exchange or ''connector'' programs where people could buy coverage, and possible buy into Medicare for those aged 55-64.

Of course, as Kanwit emphasized, attempts at any of these reforms will require making critical decisions about both the appropriate mode of regulation and whether change should be incremental or transformational. They also would raise a host of legal issues: What role will the states play, and will the standard for benefits or enforcement be a federal regulatory ''floor'' for the states versus a federal ''ceiling''? How do some of the reform measures fit into the jigsaw puzzle of existing federal legislation, such as Health Insurance Portability and Accountability Act? Are amendments or waivers to Employee Retirement Income Security Act of 1974 necessary, and if so, how do we maintain the uniformity of administration that has worked for multistate employers?

Among board members' specific predictions of incremental change in the coming year is the renewal and expansion of the State Children's Health Insurance Program, which covers 6 million children in families with income just above Medicaid eligibility and has its authorization set to expire in March. On record supporting expanded eligibility for both SCHIP and Medicaid, President Obama will find that current proposals go beyond that and call for universal coverage, which, Kanwit tells BNA, industry groups like America's Health Insurance Plans as well as the Blue Cross and Blue Shield Association support. ''Universal coverage, of course, solves a number of problems, including eliminating the need for preexisting exclusions in the individual market as well as the possibility of rescission of coverage for material misstatements on insurance applications,'' she said.

Blum agreed that SCHIP ''certainly will be renewed,'' but said state reform efforts also should be carefully watched. Those in Massachusetts and in the ''very different environment'' of Louisiana are particularly interesting, he said. On the federal level, Wall said Congress might ban physician ownership of specialty hospitals.

Nahra said he sees payment changes, new technology incentives, and changes to the purchasing side for health insurance dominating this year. Vickie Yates Brown of Frost Brown Todd LLC in Louisville, Ky., said she sees Congress continuing to use quality of care as a way to reduce health care costs and maximize the number of individuals who can be covered in programs such as Medicaid or Medicare.

Roth conveyed a novel insight on cost-saving, saying that ''just as quality of care finally became a significant issue when the Federal government figured out how to 'paymentize' and 'compliancize' it, conflict of interest also could be a hot issue in 2009 if only Congress could figure out how to use it to reduce health care costs.''

Rovner said that whenever the nation's lawmakers take up the task, ''the challenge will be whether political and societal pressure can force the health care silos to put aside self-interest for common interest and work in good faith to fix the broken American health care delivery system.''

Health care reform is so complex it "could be the Top 10 topics all by itself."

J. MARK WAXMAN, FOLEY & LARDNER, BOSTON

Rovner also said he expects that the sources of health care insurance in any reform will be a public ''baseline'' policy, much like Medicare Parts A and B, with an overlay of private insurers' policies that will give employers and individuals a wide variety of benefit packages at different price points and, it is hoped, create a vigorous and competitive market for health care financing. ''One of the most intriguing, and probably most politically charged, challenges of this approach is defining the content of the public baseline policy,'' he said. ''One

built on the Federal Employees Health Benefits Program, which is what Obama proposed during the campaign, is probably too rich to make the reform approach economically sustainable. But a public policy that provides protection for catastrophic illness/injury along with wellness/preventive care—so that it is affordable for all—supplemented by a vigorous private market of benefit packages, investment in health IT, and real reform in health care quality may just move our malfunctioning health care delivery system up the road to real health.''

The big question for 2009 and beyond will be whether the ''silos can overcome the blame game and address and correct the reasons behind this dismal performance,'' Rovner added.

Douglas A. Hastings of Epstein Becker & Green PC in Washington agreed that for changes to occur, ''payers and providers will need to find ways to shift from their decade-long focus on conflict to a focus on collaboration and cooperation.'' But he reminded readers that the U.S. health care system is a mixed public/private system and has been that way for over 200 years. ''To be effective, it requires cooperation between those sectors and within them,'' he said.

However, Hastings focused on the overarching role of the federal government. A critical element of the quality, cost, access equation is the need for the government to balance its roles as both purchaser and regulator, citing the Medicare Part D prescription drug plan as an ''extremely important example'' of a program needing coordination and balance.

Fixing the national health care system's problems and deficiencies will require policy, legislative, and regulatory changes and generate major legal issues as lawyers interpret new laws and regulations and find ways to structure transactions and new business arrangements needed to capitalize on new business opportunities, he said.

Howard A. Burde of Blank Rome LLP in Philadelphia noted that new financial institutions and investors ''already are emerging to fund health care ventures with both debt and equity. Health care will not be Wall Street's darling, but it will be considered one of the safer bets,'' he predicted.

With health care reform looming on the horizon, health lawyers ''need to be thinking ahead to the next generation'' of legal pitfalls and opportunities, Hastings said.

2. Fraud and Abuse. Government enforcement of fraud and abuse laws, particularly the False Claims Act—a reliable money-maker in hard economic times that yielded $1.4 billion in False Claims Act settlements in 2008—will be an area of significant expansion in 2009 and beyond, board members said.

Roth was one of the board members who predicted a growing FCA docket. For one thing, he said, he expects Congress to make it easier for plaintiffs to win these qui tam cases by passing legislation that would, as some describe it, ''close the loophole'' created by the Supreme Court decision in *Allison Engine*. That ruling requires plaintiffs to prove a defendant used a document or record with the intention of getting a false claim paid by the government itself, as opposed to an intervening entity. Also fueling the growth in whistleblower cases will be states' progress in enacting state false claims statutes and the federal government's tendency to use enforcement actions to effect policy changes rather than taking the slower regulatory route, Roth said.

Sanford V. Teplitzky, with Ober Kaler in Baltimore, said that state governments' becoming considerably more active in the area of False Claims investigations and prosecutions will mean that health care companies with a presence in more than one state could find themselves defending such actions in multiple states at the same time. Additionally, he said, whistleblowers ''are now including all of the states with FCA provisions in their complaints, which may considerably complicate the negotiation of settlement agreements.''

As Waxman put it, ''Like the Energizer bunny, fraud and abuse enforcement is an investment that keeps going and going. It continues to be a high priority and to yield dividends for governments to the benefit of taxpayers,'' he said.

Raskin called this area ''a perennial favorite.'' He said he sees no reason ''to believe that this will be the year that health care fraud gives up its perch atop the list. There is a huge backlog of cases that we and our clients don't even know about yet, even though they're on file under seal in some court somewhere. Expanding health care fraud prosecution is a mom-and-apple-pie issue (no public official wants to be accused of adopting a pro-fraud position) and, better yet, it pays for itself with plenty left over. Expect another big year, with a particular focus on provider relationships with industry.''

Sullivan said that ''like it or not, the government just gets better and better at routing out, prosecuting, and penalizing fraud and abuse. Some of the more recent efforts appear to be targeted toward simple recovery of overpayments and questionable payments, but the hassle factor and costs for providers will not go unnoticed.'' He predicted that if the use of private contractors to audit potential overpayments proves successful, this enforcement mechanism ''could explode.''

Nahra also expects no lag in government enforcement efforts. ''Absent a substantial turnover in top health care fraud prosecutors (which is possible but unlikely), the government will continue to pursue fraud cases aggressively, whether driven by whistleblowers or through other investigative and data-driven efforts.'' In fact, he said, the government's ability to generate its own cases through data analysis may be a significant development in its own right, particularly as developments in health information technology create ever more data for analysis.

Nahra nonetheless predicted two significant changes in the government's approach. One will be increased pressure on government health care program administrators, particularly CMS, to be more assertive on fraud ''on the front-end, with the goal of reducing the need for enforcement.'' This, he said, will include ''both program oversight and substantial pressure on the various fraud-related government contractors.

''In the same vein,'' Nahra added, ''I would expect an increased emphasis on compliance program efforts, including renewed efforts by the HHS Office of Inspector General and CMS to develop compliance guidance and otherwise put pressure on health care companies across the industry to develop and implement improved compliance programs.''

Hastings made the point that government enforcement of the FCA, the civil monetary penalties statutes, and others has a significant effect on the overall cost of care. ''The federal government has a dual role as pur-

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chaser and regulator,'' he said. As purchaser, the goal is to pay less while as regulator the goal is to require more. As purchaser it wants to encourage financial incentives to improve quality and reduce costs and help boost innovation and efficiency. But as regulator it often views incentives as suspect and possibly illegal, which can result in discouraging innovation and efficiency.

''My view is that to best achieve the goals of both higher quality and lower costs, regulatory enforcement in health care needs to shift its focus more to enhancing and supporting appropriate collaboration among providers and less to micromanaging the 'flow of funds,' '' Hastings told BNA.

Wall said that providers wanting to know where federal enforcement is going should look to the OIG work plan. ''The OIG tells us that durable medical equipment providers, physicians, and nursing homes will be the focus of scrutiny in 2009 and, based on past experience, I have no reason to doubt that.'' Wall said he expects the OIG and U.S. attorneys to increase focus on quality issues while continuing to scrutinize traditional areas of focus such as physician contractual arrangements.

The new administration and Congress are likely to be vigorous in enforcing regulatory compliance and policing fraud and abuse, especially as they look for cost savings to help fund health care reform, Rovner said. With ''lax regulation'' seen as a major cause of the Wall Street and mortgage meltdowns, the new administration is likely to seek substantial further federal involvement in health care delivery, he said. And, of course, ''increased federal involvement always brings increased federal oversight and regulation and exposure to the complex maze of federal fraud and abuse laws,'' Rovner said.

Brown agreed that Congress's efforts to curb fraud and abuse are likely to grow as part of health care reform efforts. She said she also sees reform as leading to increased compilation of health care information, helping government identify illegal activities. Since most of the data collection provisions contained in the original health care reform legislation in 1993 and in HIPAA in 1996 have been implemented, the government should be expected to use this data not only to detect payment fraud, but also to drive quality, she said.

Another fraud statute, the Stark physician self-referral law, generated a lot of board member comment. Teplitzky said there were a number of significant regulatory changes in the last quarter of 2008 that will have a significant impact on many hospital/physician joint ventures. ''The most significant changes involve the stand-in-the-shoes rule and the definition of a designated health services 'entity' that will result in many former 'under arrangements' relationships having to be unwound,'' he said.

Also focusing on Stark, Griffith said that he expects CMS will further limit the range of ancillary services that physicians can provide in their offices and bill for in addition to professional fees. W. Reece Hirsch, of Sonnenschein, Nath, & Rosenthal, San Francisco, said CMS's required disclosure of financial relationships reports, a Stark physician self-referral law compliance audit required of 500 selected hospitals, ''will finally arrive in 2009 and one thing is certain—it will cost hospitals much more time and money to complete the report than CMS estimates.''

Blum said that both Stark and gainsharing are looming issues for attorneys, with ''many new developments to be understood and absorbed.'' Teplitzky agreed that the development of new gainsharing programs is generating significant interest. He said, however, that although the OIG has issued a number of favorable advisory opinions providing anti-kickback guidance on their successful design, CMS's decision to delay the publication of a Stark exception for ''incentive payment and shared savings'' programs leaves unanswered questions regarding the parameters of a Stark compliant gainsharing program.

Mayo looked forward to a day when the law in its current form no longer is even on the books. ''Pressure just seems to grow every year to do something significant to cut back on Stark, or do away with it altogether,'' he said.

Rovner agreed the law has problems, describing it as ''ever expanding and ever more complicated.'' The Stark regulations ''just keep rolling along,'' he said. ''CMS can't seem to figure out how to get Stark regulation right, so it just keeps amending and amending and amending. And now it proposes and issues amendments by burying them in the hospital inpatient prospective payments system and/or physician fee schedule rulemaking process, which run to hundreds of pages in the *Federal Register*. It's almost as if CMS doesn't want anyone to easily find, let alone understand, what it's doing on Stark. Is this anyway to run a federal agency?'' he asked.

According to Katherine Benesch, the latest Stark regulations, published in July 2008 in the 2009 Hospital Inpatient Prospective Payment Systems final rule, have created a ''costly morass of incomprehensible and sometimes contradictory rules that are forcing providers to spend countless hours analyzing and restructuring business relationships between hospitals and physicians.

''While the leadership of both political parties goes by the mantra of 'less government,' this is one area where constantly changing government regulation greatly increases the cost and uncertainty of doing business,'' she said.

''This cost, coupled with decreased levels of reimbursement, is either being passed on to the consumer and/or driving health care providers into negative financing or out of business. Thus, regulation is driving up costs and creating a major problem in our health care system,'' she continued.

Benesch charged, ''a system where participants are penalized for alleged violations of incomprehensible rules is not functional. Change is definitely the order of the day.'' But who will lead that change at CMS is a ''fairly significant unknown,'' Teplitzky said because Don Romano and Lisa Ohrin, the two most visible CMS staff working on Stark issues, have left the agency.

"A system where participants are penalized for alleged violations of incomprehensible rules is not functional. "

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

Until change comes, however, Rovner warned he sees great danger if health care organizations facing tight budgets and negative economic pressures squeeze resources devoted to compliance too far. Given the government's continued focus on rooting out fraud and abuse, ''they may find it is a dangerous strategy that can bring a very, very expensive check later,'' he said.

Teplitzky identified another CMS rule for 2009, the ''anti-markup rule'' contained in the latest Medicare physician fee schedule, as likely to create compliance problems. The rule included significant changes to the rule for both professional and technical component billing, which ''has been a very controversial issue for almost two years, with a number of false starts.'' The rule's alterative analyses for determining when performing physicians will be deemed to ''share a practice'' with the billing physician or other supplier, thereby rendering the rule inapplicable, ''may only add to the confusion in this area,'' he told BNA.

3. Taxation. Taxation issues will remain in the forefront for health lawyers in 2009 as the already heightened oversight of the exempt hospital sector by the Internal Revenue Service and Congress continues and as the economic crisis causes financial stress for providers and their communities and threatens to swell the ranks of the uninsured further, board members said. The role of charitable hospitals also could be significantly affected depending on how health care reform efforts unfold, they added.

Howard Wall summed it up best. ''Tax exempt organizations will still be on the hot seat as the spotlight of the Senate Finance Committee continues to shine brightly on charity care and compensation practices of tax exempt providers, while IRS requires more reporting of data to establish proof of community benefits to justify avoiding the tax man,'' he said.

''Revocation of tax exemption at the state and local level, 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,'' Wall predicted.

Many board members pointed to continuing congressional oversight of the charitable hospital sector, spearheaded largely by Sen. Charles Grassley (R-Iowa), as a key tax issue in 2009, both in its own right and as a spur to IRS initiatives.

According to T.J. Sullivan, ''there is more than money at the heart of increasing IRS enforcement over the last few years, which can be expected to continue. Congressional pressure from Sen. Grassley guarantees that active and increasingly targeted IRS examination efforts will continue,'' he added.

Toby G. Singer, with Jones Day in Washington, agreed, saying she expects Grassley and the IRS to continue to focus on the problem of caring for the poor and uninsured problems and on what providers are, or are not, doing to respond. ''There will continue to be significant media attention to these issues which will create additional pressures on legislators and providers,'' she said.

Mark Waxman said Grassley will likely continue to drive an exploration of whether and at what levels there is, or should be, a difference between for profit and not-for profit health care institutions, looking at CEO compensation, the amount of charity care they provide, and the extent they engage in profit-making activities.

John Blum said charity care concerns, with increased unemployment and troubled Medicaid programs, will put a lot of pressure on health care systems caught in this bad economy.

Health care reform initiatives obviously could affect or significantly alter the exempt hospital world, several board members said.

Eric A. Tuckman, with Advisory Health Management Group, Manhattan Beach, Calif., said reforms that could encompass expanded or some type of universal coverage ''will undoubtedly require many nonprofit providers to fundamentally reevaluate the nature of the services and benefits they provide to the community in connection with their exempt status.''

According to Sullivan, ''As in 1993, as we are entering a brief and promising period in which a strong push for health care reform will raise the question of what nonprofit hospitals and other charitable health care providers must do for the public or their communities in return for exemption. If, as may be expected, the push is toward universal coverage, some may question whether there will be an ongoing need for charity care or access for the uninsured.

''Also as in 1993, one hopes that responsible voices in and out of government will recognize that there always will be demand for services by individuals who fall through the cracks, such as illegal aliens or those unable or unwilling for individual reasons to qualify for coverage and that there is a much broader array of benefits that nonprofit providers provide to their communities beyond uncompensated care,'' he said.

''While the issue is likely to get discussion as part of the overall reform effort, my own view is that we will not see significant change in the standards for tax exemption for health care organizations at the federal level over the next few years,'' he added.

Sullivan also said he expected executive compensation will be a primary focus at the IRS and elsewhere. ''As the late Tim Russert might have said, 'Compensation, compensation, compensation.' Even in characterizing the much heralded full report on community benefit stemming from its 2006 compliance initiative, the IRS has already signaled that the big issue in its view is compensation,'' Sullivan said.

Michael W. Peregrine, with McDermott Will & Emery, Chicago, agreed. ''The long-awaited final IRS report on executive compensation practices is expected to conclude that, while high executive compensation is paid by tax exempt hospitals, compensation amounts are generally defensible because the organization is entitled to the rebuttable presumption of reasonableness,'' he said.

This will fuel concerns at the IRS, with the Senate Finance Committee, and with the media and the public that satisfaction of the rebuttable presumption may not

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be enough to curb what some believe are unreasonably large increases in executive compensation amounts, he added.

Gerald Griffith predicted the IRS ''will also strike with another wave of hospital compliance checks, this time focusing on unrelated business income and modeled on the college and university questionnaire sent out in October 2008.'' He also predicted ''major tax law whistleblower cases will begin to surface in health care'' under procedures adopted by the service to allow such claims in December 2007.

Board members also pointed to exemption revocations and associated litigation in the states as an important component of the 2009 landscape. Waxman, for example, said he expected taxing authorities at the local level ''to continue to make inroads on the tax-exempt classification.''

Sullivan agreed, predicting the possibility of ''dramatic developments'' at the state level, most notably in Illinois. ''The hospital industry there will either be blessed by a favorable Supreme Court ruling on the standards for charitable exemption or will be forced to petition the state legislature for relief, at which point compromise is likely to require some level of minimum charity care expenditures in return for continued property tax—and sales tax—exemption.''

Fredric J. Entin, with Polsinelli Shalton Flanigan Suelthaus PC in Chicago, agreed about the importance of the Illinois Supreme Court's decision to grant review in litigation involving whether Provena Covenant Medical Center in Urbana, Ill., qualified as a charitable or religious organization entitled to a property tax exemption in the 2002 tax year.

''While Illinois has been the most aggressive state in mounting challenges to hospital tax exemptions, the actions taken against Provena and other nonprofit health care providers in Illinois raise legal issues under examination across the country,'' he said.

''Significant declines in property values have reduced revenues for counties and other local instrumentalities of government already struggling to fund local services and infrastructure,'' Entin said. ''As has been seen in other down economies, when traditional sources of revenue decline, taxing bodies look closely at the amount of property off the tax rolls and begin to challenge exemptions,'' he added.

Entin noted that approximately 20 states have mandated community benefit reporting requirements, and at least an additional 16 states have voluntary community benefit reporting through the state hospital associations. This data will enable them to make more considered judgments on the value returned by non-profits as consideration for tax exemption.

As with the reporting now underway in states with such requirements, the new Schedule H to the IRS form 990 will enable policy makers to make more informed judgments about the suitability of the current standard or a more formulaic approach to charity care, Entin continued. ''Just as with the states, economic struggles may accelerate activity at the federal level challenging exempt tax status for nonprofit health care providers,'' he added.

Sullivan said that ''There is no longer much room to maneuver in completing the new 990, so organizations should expect increased scrutiny at the local level over the next few years and possible congressional scrutiny once national data becomes readily available.'' Data from Form 990 filings will not only help inform discussions concerning charity care and community benefit it should be a valuable resource for comparability data to establish reasonable compensation, he added.

In addition, Sullivan continued, ''while there were few developments in the area of tax-exempt HMOs during the early 2000s, the Vision Service Plan litigation, now pending before the United States Supreme Court, creates at least some uncertainty over the status of the law with respect to Section 501(c)(4) tax exemption for nonprofit HMOs.

''Although the Supreme Court is widely expected to deny review of the underlying appellate decision, consolidated VSP litigation in federal court in Ohio will keep the issue of qualification for 501(c)(4) exemption, and concerns about the poorly-reasoned district court opinion from the first VSP case, on the front burner,'' he said.

4. Health Information Technology. Health information technology issues remain in the Top 10 because, board members said, they permeate just about every other Top 10 category. Whether it is because of the relationship between HIT and quality improvement or the nexus between HIT and cost containment and efficient delivery of health care services, most health lawyers recognize that HIT will be a key component of whatever reform efforts unfold, they added.

Add to that the significant challenges posed by HIT technological and cost issues, related physician resistance, patient privacy concerns, as well as fraud and abuse implications, and it quickly becomes clear why adoption and implementation of HIT shines as one of the preeminent legal issues that will face the health care industry in the coming year, they said.

According to Kirk Nahra, ''There already have been strong indications—from both the incoming Administration and Senate Democrats—that health information technology will be an important component of overall health care reform efforts. In fact, there is an almost impossible-to-meet set of expectations—in terms of financial savings—driven by improved efficiency from health information technology.

''These goals will be put into direct conflict with a parallel set of interests related to privacy and security in the health care area and Congress and the new Administration will struggle to balance the need for privacy—including the question of whether there are 'new' needs in this area—with the potential gains from health information technology,'' Nahra added.

Richard Raskin agreed, saying HIT ''will be at the core of both major and minor health care reform proposals. The task of regulators and industry will be to continue to drive innovation while developing standards and addressing the hardest question—who will pay?''

Mark Kadzielski said ''the electronic medical record (EMR) is the technological cornerstone of HI in this decade—however, there are many stumbling bocks to its successful operational reality. Cost is only one factor.

The next few years will see no ''significant change in the standards for tax exemption for health care organizations at the federal level.''

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

''The many concerns about serious breaches of patient privacy are magnified by the existence of an EMR that is readable by so many from so many access points. Effective security controls, and serious punishments for those who breach patient privacy, will be one of the major issues facing health care providers who are able to implement the EMR in 2009,'' Kadzielski added.

Interoperability and other thorny HIT implementation issues may have to be addressed by Congress head on, several board members suggested.

Fred Entin observed that health care IT systems have continued to be resistant to universal interoperability and that, ''instead of relying on the market to sort out the process, the new administration may choose to mandate standards to accelerate the use of IT in health care delivery.''

Stephanie Kanwit said that, ''While comprehensive health information technology legislation has not to date been approved by Congress, it's expected that renewed efforts will be made to pass such a bill next year, including requirements impacting privacy and data security.''

Kanwit noted that states also are proposing a number of initiatives to promote the adoption and use of health information technology. ''The key to both the federal and state efforts is interoperability—to ensure that users of this technology can communicate and exchange data accurately with different IT systems,'' she added.

According to Vickie Brown, ''The use and compilation of health care information will continue to be important in 2009 and as health care reform is implemented and will be helpful in the government's efforts to identify fraud and abuse and in implementing practice parameters to achieve the government's idea of quality of care.''

Along with Nahra, several board members pointed to the tension between HIT adoption and protection of patient privacy as a major impediment to HIT adoption that remains unresolved.

Jack Rovner said that HIT implementation initiatives will bring with them calls for better solutions to protecting and managing the privacy and security of health information. ''The spread of state security breach notice laws, the growing threat of medical identity theft, compliance with stop gaps like the 'Red Flags' Rule, the introduction of 'vault' vendors for consumers to control their own personal health records, all perpetuate a hodge-podge of data protection requirements that pose substantial obstacles to effective adoption of interoperable electronic health records and other e-health initiatives,'' he said.

Katherine Benesch noted that, ''The availability of health information continues to increase with both positive and negative effects especially given that, with electronic medical records, online personal health information is easier to access, and more difficult to protect.''

Other board members focused on the fraud and abuse implications for HIT adoption.

''We are constantly receiving inquiries from clients as to the parameters of permissible arrangements to provide e-prescribing and e-health records technology to physicians,'' Sandy Teplitzky said. ''While the goal is often improved patient care, the concern is usually trying to avoid a Stark or anti-kickback problem,'' he added.

Nahra observed that the government's ability to use HIT to generate its own cases through data analysis may be a significant development in its own right, ''particularly when coupled with the HIT developments that will create more data for analysis.''

Another area involving HIT relates to the question of enforcement. ''I would expect to see significantly more enforcement action by the new administration under the HIPAA Privacy Rule and would expect this to occur relatively quickly, with the HHS Office of Civil Rights and others being given strong marching orders to increase enforcement efforts related to privacy breaches and other privacy violations,'' Nahra said.

Reece Hirsch agreed. ''In November, the OIG issued an audit report that took CMS to task for ineffective enforcement of the HIPAA Security Rule. I think it's very possible that the OIG report will serve as an impetus for more HIPAA security enforcement actions from CMS in 2009,'' he said.

''As a result of this report,'' said Elisabeth Belmont, with MaineHealth in Portland, Me., ''CMS likely is feeling pressure from OIG to be more vigorous, aggressive, and proactive in its enforcement of the HIPAA Security Rule and we will see more activity in this area in 2009.

''Because a hospital's security compliance deficiencies and vulnerabilities are often not evident to its patients, the Security Rule has not been a particularly good fit for an exclusively complaint-driven enforcement program. Health care providers will need to evaluate whether their HIPAA Security Rule compliance programs would withstand the scrutiny of a CMS Security Rule compliance audit,'' Belmont said.

Medical identity theft also will continue to be a major challenge for hospitals in 2009, Belmont said. ''Theft of confidential patient information, which is often an 'inside job' by billing or other hospital staff who have access to Social Security and health insurance policy numbers, likely will be the focus of future security audits in 2009,'' she said.

Nahra also said he expected to see an increasing debate about whether state-based initiatives related to health IT and privacy are useful or counter-productive, particularly where efficiency gains are such an important part of the overall reform model.

Kadzielski said he expects new provider regulations on the state level to be implemented to tighten the oversight of health care providers. ''New fines for violations of patient privacy, for example, are already being used as a method of both deterring such behavior as well as a source of funding for cash-strapped state agencies,'' he added.

Finally, several board members, such as John Blum, pointed to the interplay between electronic medical record systems and electronic discovery. ''Basic questions involving the definition of the electronic medical

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record and complex discovery issues must be confronted,'' Blum said.

Belmont agreed. She cited hospitals lack of preparedness for the discovery-related challenges of electronically stored information (ESI) and underlying metadata. ''Some experts have talked about a 'readiness gap' among hospitals, meaning they are not doing what they should be right now to prepare for litigation that may require them to produce ESI,'' she said.

''Much of the recent focus in e-discovery is on the statements made in voluminous e-mails and the need to find and preserve evidence for cases involving employment discrimination and securities law violations,'' she said. ''Although e-mail is not widely used in patient-provider care, it will be of significance in many other areas—such as disputes with payers, Stark and anti-kickback law compliance, and antitrust claims—that may be the subject of communication at the administrative level in health care organizations,'' Belmont added.

E-discovery also will implicate more and different type of information, she said. This includes software application metadata and other information that can reside in numerous locations, many of which are controlled by physicians, labs, and others who are not employees of the litigants, Belmont said.

''EHRs generally include the same information found in a paper chart, as well metadata identifying who made or edited each entry, who merely accessed the record and when such activity occurred,'' Belmont continued. ''Not all plaintiffs counsel realize yet how much metadata exists in EHRs, computerized physician order entry systems, and other information systems, but discovery demands are likely to increase significantly as this awareness grows,'' she added.

Belmont concluded by noting that the associated costs also make e-discovery a significant concern for hospitals. ''Some,'' she said, ''are reporting that the costs of e-discovery are being used as a weapon to compel earlier and more expensive settlements.

''The costs include both the internal costs of taking key IT, records management, and legal personnel away from their regular duties as well as the external costs of data retrieval and analysis,'' she said.

5. Quality. Last year, *HLR*'s experts called health care quality the ''issue of the decade''—a sentiment still maintained by Doug Hastings. This year, however, some are wondering if patient safety and quality of care will be sacrificed on the altar of economic recovery efforts.

John Blum, for example, warned that patient safety initiatives may falter due to the state of the economy. If health care providers are forced to lay off workers, staffing shortages will pose challenges for risk management and may halt the momentum that has been building in the quality of care arena. Also, he said, the new Patient Safety and Quality Improvement Act regulations, released Nov. 21, 2008, are ''overly complex.''

But, said Sandy Teplitzky, ''too much attention has been paid to the issue of improving quality during the last 18 months for this issue to go away.''

Howard Wall said he sees ''new and complex'' issues emerging in the field of health care quality. ''Everybody'' is focused on improving patient safety, he said, including the HHS OIG, the Joint Commission, the Department of Justice, and CMS. ''The perception in Washington is that our health care system is broken—that we are not getting the quality we deserve for the dollars we are spending,'' he said.

Responsibility for improving quality will fall more and more on hospital boards of directors, two board members noted. Doug Hastings, for example, said quality of care now is being widely recognized as a health system board fiduciary responsibility.

Nearly all of the board members cited financial incentives as the chief means of improving quality of care. Teplitzky, for example, said he foresees continued development of pay-for-performance (P4P) programs and ''tweaks'' to Medicare's ''never events'' regulations. He cautioned, however, that refusals to pay for poor performance could lead to ''paying only for excellence.'' ''In other words,'' he said, ''qualitative decisions may be made before any payment is made.''

Financial incentives, Hastings said, will ''create a new generation of hospital-physician financial relationships, including a much broader level of gainsharing-type arrangements.''

Fred Entin, too, thinks that payment incentives will become a popular method to increase quality of care in the coming year. Such incentives will encourage greater integration of care, the adoption of evidence-based decision making, and measurement and transparency of outcomes, he said.

Additionally, ''negative incentives will also encourage hospitals to implement quality programs as the number of 'never events' for which reimbursement will be reduced or curtailed will increase,'' Entin said.

Mark Kadzielski called this ''the new era of NP4NP, or 'no pay for nonperformance.' '' He also predicted that the list of ''never events'' will expand in 2009 and that ''quality managers will be under increased pressure to avoid such events from a financial perspective.'' Kadzielski noted that the states are getting involved in this process. In California, for example, hospitals ''are already being 'punished' for adverse events by significant fines being levied by state regulators; fines for these events will increase in 2009,'' he said.

Mark Waxman said P4P programs will continue to expand, though he questioned whether such programs ''will truly be maintained and effect change, or will become capital-based programs that will be driven by economics alone.''

''The OIG's recent advisory opinion on gainsharing is a very encouraging sign for hospitals trying to put together P4P and other gainsharing programs with staff physicians,'' Reece Hirsch noted. ''The main problem is that CMS has not issued its opinion on the Stark implications of the arrangements. It's a little like having a traffic cop wave you forward with one hand while signaling that you should stop with the other,'' he said.

Quality of care is improving now that it is being tied to compensation, according to Katherine Benesch. ''The real question is how to measure the causal relationship between improvements in quality that are caused by providers, as opposed to those quality improvements caused by other factors,'' she said. Although some quality measures are easy to quantify—e.g., decreased length of hospital stay, fewer medical mishaps—''true measures of quality are very difficult to evaluate,'' she noted.

One possible contributor to quality improvement is new medical technology, Benesch said. For example, an increased use of electronic medical records should lead to ''increased continuity and quality of care'' over time.

However, Benesch sees questions arising over the availability of new technologies and the extent to which physicians and patients in certain areas may benefit from them, while those in others may not. ''Does this favor physicians in large academic medical centers, as opposed to those in small hospitals and rural areas that do not have the same resources?'' she asked.

''Inexplicable variations in care, too much medical care that is not based on evidence, and a high number of medical errors are still with us.''

STEPHANIE W. KANWIT, AMERICA'S HEALTH INSURANCE PLANS, WASHINGTON

Fred Entin agreed that ''effective quality programs are highly dependent on information technology.'' The importance of investing in IT is particularly important in clinical integration programs, for example. However, Entin said, there are barriers to the adoption of IT in individual physicians' offices that must be resolved.

Stephanie Kanwit observed that, ''unfortunately,'' some of the same issues related to quality that have existed for years, including ''inexplicable variations in care, too much medical care that is not based on evidence, and a high number of medical errors are still with us.'' But, she added, ''solutions to improving quality are out there.''

''Watch for additional vigorous incentives on the part of both public and private programs to develop and improve quality measures and measurement, increasing the number of Medicare pilot programs as well as state Medicaid programs, for example, that already operate P4P initiatives,'' she said. These programs, which go by various names, ''are all based on recognizing high-quality providers, incentivizing improvement by all providers, and empowering patients to use that information in making their own health care decisions,'' Kanwit added.

Also, ''watch also for advocates to insist that quality requires that we follow the role model of most European countries and set up a federal agency that objectively evaluates the efficacy of new, as well as existing, drugs, devices, therapies, and other health care services.'' This would enable ''both public and private systems to reward patients and practitioners for the use of high-value tests and treatments,'' Kanwit said.

Jack Rovner suggested that ''meaningful and effective oversight'' of the health care system is needed, rather than reliance on tort law to enforce safety protocols. ''We would never allow the tort system to be our primary means of enforcing safety obligations on the airline industry, and we don't allow airlines to police themselves for safety compliance,'' he wrote. Referring to statistics from Sen. Max Baucus's ''Call to Action'' study showing that adults receive the right care only 55 percent of the time and children less than half of the time, Rovner asked: ''Would anyone fly if airlines crashed 45 percent of the time?''

Richard Raskin called quality of care a ''key part of health reform packages, and potentially an important part of payment reform.''

Hastings noted that care coordination, a part of President-elect Obama's health care reform plan, may prove effective to improve quality and control costs. If it is to succeed, though, the regulatory system ''must shift its focus to enhancing and supporting collaboration among providers and away from micromanaging the 'flow of funds,' '' he added. ''There is an opportunity for the best performers in the industry to create profound change, and then to open up best practices through transparency of data and to promote collaboration to spread positive change,'' he said.

6. Medical Staff. Last year, several *HLR* board members saw a collision coming between medical staff and hospitals over the Joint Commission's revision of Medical Staff Standard 1.20 (MS 1.20) to mandate that certain requirements be included in the medical staff bylaws and to allow the medical staff to bypass the medical executive committee (MEC) and take issues directly to a hospital's governing body.

But that collision did not occur in 2008, and likely will not occur in 2009, according to Howard Wall, because the JC suspended the July 2009 implementation date for MS 1.20 and established a new time line for the revision. As a result, Wall said, hospital boards of trustees will continue to be responsible for what takes place inside the hospital, including quality issues, and the MEC will continue to be a powerful voice for the medical staff.

According to Mark Kadzielski, new JC requirements ''of ongoing and focused professional evaluations are slowly taking hold at hospitals and will be a key element of Joint Commission surveys in 2009.'' These requirements are leading medical staffs to ''more properly focus on reviewing the quality and competence of their members,'' he said.

However, another move by the JC has raised concerns for health care providers: its ''surprise adoption'' of a physician disruptive behavior standard last summer and its revision of the leadership chapter, both effective January 2009, to require better communication about quality of care and patient safety and more effective conflict management. These standards ''will set the stage for potential conflicts in 2009,'' Wall said. He noted that the American Medical Association has asked the JC to delay enforcement of the disruptive behavior policy.

More fundamentally, there will be significant changes in the relationships between hospitals and their medical staffs, several board members said. For example, Gerald Griffith foresees ''increases in hospital acquisitions of physician practices and employment of physicians in all specialties.''

Mark Waxman agreed that physicians increasingly will look to being employed by hospitals, hospital systems, and large physician groups, rather than opting to practice in solo or small group environments.

Collaboration may become a buzzword. ''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,'' according to Doug Hastings.

Hastings said he believes ''a radical shift in the locations and economics of health care delivery'' is on the

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way, triggered by changes in population demographics and technological innovations. Another factor likely to have an impact on the economics of health care is the rise of specialty hospitals and other physician-owned entities that compete with hospitals, Howard Wall said.

Wall added that a rift is growing between staff physicians and hospitals over on-call issues. ''With the number of hospitals now paying specialists to take calls at 40 percent nationally, the question of who has an obligation both legally and ethically to care for patients who come to the nation's emergency rooms for their emergency and nonemergency heath care needs will continue to be debated,'' he said.

Tom Mayo agreed that on-call issues are straining physician-hospital relations. Usually, the medical staff's on-call obligations are spelled out in the medical staff bylaws, he explained. But lately physicians have been ignoring those obligations, saying they will not honor them unless they receive additional compensation. This has led some hospitals to contract separately with the medical staff for on-call coverage. Theoretically, hospitals could terminate the staff privileges of physicians who refuse to provide on-call coverage, he said, but they usually do not.

The conflict may become most acute for hospitals with regard to their obligations under EMTALA, the federal law that governs hospital emergency services, both Mayo and Wall noted. And that strain could become even more pronounced in the near future, according to Katherine Benesch.

As the economy worsens and more people are laid off, Benesch said, the number of uninsured individuals will rise. This, in turn, will lead to an increase in the number of people using hospital emergency rooms for primary care and for true emergencies that result from delaying necessary preventive care. Under EMTALA, emergency rooms cannot turn those patients away—they must be reviewed and stabilized before being transferred to an appropriate facility for care, she said. Yet, there is no provision in the law for paying hospitals or doctors for the costs of the review and stabilization.

''This is another one of the many sets of regulations that mandates the provision of care without a corresponding payment to cover its cost,'' Benesch said. ''As long as these unfunded mandates increase, they contribute to pushing hospitals toward the brink of financial insolvency.''

Another issue that may lead to discord between hospitals and medical staff in 2009 concerns physicians' conflicts of interest.

Bob Roth noted that Congress currently is very interested in relationships between physicians and pharmaceutical and medical device companies, and is considering legislative proposals to require disclosure of all income, including speakers' honorarium, physicians receive from these entities. Failure to disclose such income could lead to tort claims or even criminal sanctions, he said.

In particular, the Physician Payment Sunshine Act (S. 2029), introduced in 2007, would require the drug and device industry to report the value of any payments to doctors, as well as the purpose of the gift. Since it was introduced, the Senate version has been revised and has picked up the endorsement of device industry groups. A nonidentical House companion bill (H.R. 5605) also still is pending.

Despite Congress's failure to date to pass a transparency bill, pharma and device industry groups, as well as physicians' associations, have adopted voluntary disclosure recommendations, individual companies have announced that they will make public their payments to physicians, and universities have restricted the use of industry funding for research and education, Roth said.

Waxman agreed that the ''relationship between physicians and pharma and medical device companies continues to be a subject of increasing scrutiny.'' He predicted more movement in 2009 on the state level, citing legislation enacted in Massachusetts in 2008 that essentially imposes a ''gift ban'' on physicians. He expects more states to adopt laws modeled on the Massachusetts statute.

Sandy Teplitzky also predicted that pharmaceutical and device makers will come under increased pressure in 2009 to disclose payments made to health care professionals to promote their products. He is concerned, however, that this trend will ''call into question legitimate and necessary arrangements intended to promote research and product development.'' Teplitzky, too, sees more movement in the states in this area, including state prohibitions or severe limitations on industry payments to physicians.

More traditional medical staff issues also will continue to be of concern throughout 2009. ''Liability issues surrounding peer review, mollified somewhat by the Fifth Circuit's rejection of the *Poliner* judgment, still are a major driver of how peer review actually gets conducted in hospitals,'' according to Mark Kadzielski. Also, he said: ''Concerns about negligent or misleading referrals, highlighted in the *Kadlec* case, continue to hang over the critically important credentialing process at all health care organizations.''

7. Antitrust. Antitrust law makes the Top 10 list again primarily because of economic pressures that will continue to spur consolidations in health care sectors and because a new administration is expected to make antitrust enforcement by the Federal Trade Commission and Department of Justice a higher priority than it was in the Bush administration, board members told BNA. Private enforcement of state and federal antitrust laws also is expected to increase in this environment, they added.

HLR board members said they expected health insurers and the pharmaceutical industry to garner increased scrutiny from federal enforcers while overarching quality and economic concerns, and related pressures to adopt health information exchange systems and other expensive technologies, will place provider integration activities under a brighter spotlight.

Toby Singer predicted greater enforcement of the antitrust laws in the new administration and in general, noting that the president-elect already has said he'd pay more attention to insurer consolidation. ''Private antitrust litigation will also continue to be active, especially in the economic credentialing area and where competitors are excluded from provider networks,'' she added.

Douglas Ross, with Davis Wright Tremaine LLP in Seattle, said antitrust issues will continue to arise as economic pressures and other forces lead hospitals to consolidate over geographic regions and push hospitals and physicians to integrate. He said he expects the FTC will continue to be active but that it may be more recep-

tive to efficiency arguments than it has been in the past few years.

''However, despite the campaign rhetoric from the Obama campaign that it will enforce the antitrust laws more vigorously than the current administration, the pressure of a declining economy, red ink or close to it on many hospital bottom lines, and physician fears to strike out on their own could prevent the FTC from becoming more enforcement oriented than it already is,'' Ross said.

''The concept of clinical integration likely will be tested in court and, where it can be shown to clearly exist and clearly drive quality, clinical integration will be an important antitrust defense.''

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

According to Fred Entin, ''Many expect a Democratic administration and Congress to encourage a more aggressive enforcement program by the DOJ and the FTC. Further, the Democratic controlled Congress will be filling several vacancies on the FTC. How politics influences the policies of these agencies will bear close watching but it is not a reach to conclude that the prevailing enforcement attitude will be more hands on than the last eight years.''

Jack Rovner cited government victories in the Evanston Hospital and North Texas physician cases as likely to embolden antitrust enforcement in health care, especially as the new administration and Congress are likely to favor vigorous antitrust enforcement. ''Look for greater scrutiny of hospital and health plan mergers, as well as continued and perhaps enhanced policing of physician and other provider cartel activity,'' he said.

John Blum noted that, ''while there is a large gulf on the quality side between stable and troubled providers that is already leading to consolidations, economic realities now may force those consolidations.'' These consolidations may not be blocked by antitrust laws, but they will certainly be scrutinized under them, he added.

Doug Hastings agreed, saying that, in the wake of the Evanston case, hospital mergers going forward will be scrutinized more closely. ''Constant consolidation on the one hand and expansion into new product markets on the other creates antitrust issues that will make headlines,'' he said.

''The concept of clinical integration likely will be tested in court and, where it can be shown to clearly exist and clearly drive quality, clinical integration will be an important antitrust defense,'' he also predicted.

Mark Waxman said that, whether or not the new administration steps up enforcement in the health care industry, particularly in the realm of consolidating insurers, the number of private cases will rise. ''As the market consolidates, there will be increased pressures on those who feel the brunt or who are rejected by the consolidators to air their grievances,'' he said.

Howard Wall cited recent cases involving physician-owned specialty hospitals, major hospitals, and health plans as evidence that anti-competitive conduct is on the rise. He predicted that a government enforcement approach, ''which has of late favored market forces to self-regulate, may give way to more active regulatory activities as unions and consumers raise objections to market consolidation activities that may result in fewer consumer choices.''

Richard Raskin agreed that economic forces will drive providers to look to consolidate and predicted that consolidations may motivate class action plaintiffs to bring new cases. ''As international developments will open new avenues for enforcement overseas, particularly in the pharmaceutical and medical device sectors, I would expect more big cases,'' he added.

Eric Tuckman said ''economic pressures that are attendant to the normal economic cycles in the hospital industry, along with the unprecedented national financial crisis, will certainly result in an increase in cooperative activities, joint ventures, and outright mergers and acquisitions.

''The dramatic deterioration of health care capital markets will also serve as impetus to coordinate and avoid/minimize duplicative capital/operating expenditures,'' he continued. However, ''the benefits associated with the development of new regional health care delivery systems may cause a direct conflict between economic realities, health care financing reform, and existing antitrust policy,'' he added.

T.J. Sullivan summed it up. ''The government's seeming ambivalence about antitrust enforcement and its backward looking focus on mergers from previous decades will likely give way to at least some stepped up advance consideration of hospital and health plan mergers,'' he said.

''The government is no doubt feeling a little stronger after the conclusion of its case against Evanston Northwestern and its effective stalling of further consolidation in Northern Virginia and, with a new president and team at the helm, it may again feel empowered to carefully review further consolidation,'' Sullivan continued. ''For hospitals facing the combined pressures of serious access to capital issues and challenges to investment income, the delays resulting from those reviews may be just what the doctor did not order,'' he concluded.

8. Medicare. Medicare remains an overarching and far-reaching component of the U.S. health care system and will continue to drive, as well as reflect, the significant changes most board members said they expect to see during 2009. In addition to Medicare's central role as part of any health care reform initiatives, regulatory and compliance issues under Medicare Part D, concerning Medicare managed care, and arising under the Recovery Audit Contractors (RAC) program are expected to garner the attention of health lawyers this year, they added.

And whether or not health care reform initiatives work major changes in Medicare program design or operation, it will be the subject of significant debate as the costs of treating the aging baby-boomer population continue to loom large on the horizon, they said.

According to Doug Hastings, Medicare remains a Top 10 issue because the federal government is such a huge purchaser of care that its coverage and payment policies affect the health care system more than any other entity. ''For the federal government, balancing its roles as both purchaser and regulator is a critical element of the quality, cost, access equation,'' he said.

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Bob Roth agreed. ''Given its size and leadership role on regulatory issues, Medicare must be included as a Top 10 issue,'' he said. That is so even before you consider the increased focus on Medicare Advantage and Part D program compliance matters and audits that is expected, he added.

With respect to reform, Mark Kadzielski was somewhat circumspect on the prospects for major changes in the Medicare program and said Medicare will be a central force in health care even without major reform.

''Funding cuts loom large and the practicalities of the governmental priorities that are focused in other directions means that some aspects of Medicare programs will face reduced reimbursement,'' Kadzielski said. ''The recent Medicare promulgation of three National Coverage Decisions for surgical-related 'Never Events' is just one step in such a direction—that will deny more payments to more health care providers in 2009,'' he added.

Vickie Brown predicted that Congress will continue its efforts to integrate and tie quality of care with payments to providers and will continue to implement the pay for performance and physician quality reporting initiative efforts.

Sandy Teplitzky said he expected there could be action with respect to physician reimbursement and the Part D program. ''While I have no specific information, numerous questions were raised by Democrats during the election campaign as to the enormous costs of this program. I suspect that if there is to be any action on this issues, it will happen quickly,'' he added.

Kirk Nahra said that, although there was ''nothing dramatically new here, Medicare remains a Top 10 issues because it is another pressure point and because I expect increased enforcement under Part D and newer and increased pressures related to the managed care activities.''

He noted that health insurers ''are—again, perhaps unfairly—a key target of legislative and enforcement attention'' and that there will be ''increasing pressures to reduce payments to Medicare managed care plans, while at the same time trying to encourage increased use of some other Medicare programs.''

He also said he expects to see ''continued enforcement efforts against health plans, both through administrative channels—such as more aggressive enforcement under Part D—and through traditional litigation action, driven in part by whistleblowers who now see health insurers as a target in the same way that providers have been for many years.''

The area providing the largest challenges for practitioners is the RAC program, several board members said. Teplitzky, for one, said ''RAC audits and appeals will continue to consume a significant amount of time and interest. While the industry experience with respect to appeals has been favorable to date, the time and expense of such appeals remains a concern,'' he added.

Fred Entin agreed. ''Many who have experienced an audit complain that the amount of documentation requested by the auditors is excessive and unnecessary. Although appeals available for contested audit results have been highly successful, they are costly and may exceed the resources available to mount a successful appeal,'' he said.

Medicare's RAC program also is expanding in 2009 beyond its three-state pilot program. Implementation of the permanent RAC program—which must be completed in 2010—was delayed until early 2009, pending a Government Accountability Office review of two contract award protests.

The expansion means that additional states will see RAC audits in 2009, Entin noted. ''While the purpose of a RAC audit is to find underpayments and overpayments, the vast number of audits have found overpayments,'' he noted.

''Given competing priorities for government, there is reason to expect government officials will welcome the return of millions of dollars from aggressive audits. And aggressive audits can be expected since auditors are compensated on a contingency basis, thrusting hospitals into a new and confusing series of inquiries into medical necessity and coverage,'' he continued.

''Rulemaking may address some of the problems experienced in the pilot states, but the spread of RAC across the country will result in more audits and appeals,'' Entin said.

''An interesting collateral issue that may emerge from a RAC audit will be the linkage of a finding of no medical necessity and medical malpractice,'' he observed, adding ''questions will arise whether a RAC finding is admissible evidence of a deviation from the standard of care and whether, such claims should be covered by liability insurance.''

9. Labor and Employment. The big news in labor this year, according to several board members is the expected enactment of the ''Employee Free Choice Act,'' an initiative passed by the House in March, but defeated in the Senate in June. ''This legislation is certain to be reintroduced in the next Congress, according to Fred Entin. It has a good chance at passage since, Howard Wall said, it has the backing of the incoming administration.

The legislation would give workers the option to choose union representation by signing authorization cards, with the National Labor Relations Board performing a card check to determine whether a union has majority support. Critics of the measure have said it eliminates the secret ballot method of voting for union representation, allowing for identification of employees who refuse to sign cards and leaving them vulnerable to intimidation by pro-union employees. Most health care industry and business leaders consider it to be ''radical pro-union, game changing legislation,'' Wall said.

In the past, organized labor has had only modest success in organizing health care workers, Entin noted, but the EFCA could change that. ''Without the need to go through an election with secret balloting, and without the ability of management to communicate with workers regarding the pros and cons of unionizing, labor would have an improved likelihood of organizing hospital workers,'' he said.

Depending on the final form of the act, Entin said, ''hospitals will face increased efforts to organize and, in hospitals not previously unionized, employee-management relations will be altered significantly.''

T.J. Sullivan called the EFCA the ''Holy Grail for unions'' and noted that it ''may be delivered as part of the spoils for early union support of President-elect Obama's candidacy.'' It remains to be seen, he said, whether some of the more objectionable portions of the proposals to date ''can be knocked out.''

Toby Singer predicted that, with the coming of the new administration, labor unions will get stronger and

the NLRB will become more active, while Mark Waxman noted that the Service Employees International Union and other unions have identified the health care industry as a ''key target'' for unionization activity.

The Employee Free Choice Act is ''radical pro-union, game changing legislation.''

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

Gerald Griffith, too, foresees ''renewed vigor of unionization efforts in health care,'' fueled by the EFCA. Unlike the others, though, he noted that there may be record layoffs in the health care industry due to the overall slowing of the economy.

Doug Hastings agreed that the EFCA, if passed, ''will dramatically change the landscape for union elections.'' He noted that, in addition to increased union activity at hospitals, the slowing economy, the trend toward employed physicians, and continued staffing shortages ''all add up to a robust year in health care labor and employment law.''

Labor trends other than increased union activity likely to impact the health care sector in 2009 include the shortage of health care workers, several board members said.

Entin said these shortages ''will severely tax the future ability of our health care system to adequately care for Americans if solutions and strategies are not implemented soon.'' Along with the rest of the baby boom generation, nurses, physicians, and other health care professionals are getting older, and the number of younger people graduating from training programs ''is not keeping pace with those leaving the profession,'' Entin said.

With physicians, for example, fewer who are just entering practice are choosing primary care over specialties, Entin said. This is most likely due to declining incomes, pressure from payers to handle more patients, and the high cost of practice, he noted. However, there are possible solutions in the works, such as ''medical home'' projects to supplement income for primary care physicians based on quality of care and implementation of residency programs in underserved areas, Entin said. He proposed that hospitals should begin to explore ways of providing incentives for their employed physicians to focus on primary care.

Howard Wall added that the shortage of nurses, physicians, and other health care workers ''will continue to shape the crises of health care labor shortages.'' He predicted that many hospitals, especially those in rural areas, soon will find it impossible to recruit specialists in highly valued specialties, such as cardiology and orthopedic surgery. In addition to the aging of the health care workforce, he cited the tightening of U.S. immigration laws and their effect on hospitals' recruiting of foreign-born doctors as contributing to the shortage.

Richard Raskin said labor issues do not usually make his Top 10, but he made an exception this year due to the ''spread of wage and hour class actions.''

10. Corporate Governance. Board members said corporate governance remains a Top 10 issue for 2009 as economic and compliance pressures—whether related to fraud, quality, competition, compensation, or employment concerns, to name only a few—force corporate boards to be more and ever vigilant in minding their oversight of, and fiduciary duties to, health care payers and providers.

Michael Peregrine said the current economic crisis ''may fairly be expected to have a broad-ranging impact on corporate boards, whether for-profit or nonprofit.'' The governmental response to the crisis ''is likely to prompt an extraordinary climate of accountability, in which 'finger pointing' and attempts to assess responsibility will be the order of the day,'' he said.

''Further efforts to promote self-regulation are likely to fall on deaf ears'' and this ''ugly climate will be compounded by the realization that Sarbanes-Oxley may not have been the 'magic elixir' of corporate governance it was intended to be,'' Peregrine said. ''The attentiveness and responsiveness of corporate boards will be at the center of the resulting storm.''

Kirk Nahra agreed that a renewed emphasis on the efforts to police corporate activity will be another offshoot of the current economic pressure. While much of this will stem from the increased emphasis on the importance of compliance programs in the health care industry as a whole, ''we can expect to see additional investigations of overall corporate governance as the current economic pressure and the desire for health care reform coalesce,'' he said.

Richard Raskin and John Blum agreed. While corporate governance is ''bread and butter stuff, it remains important, particularly in an era where provider relationships with industry are so closely scrutinized,'' Raskin said. ''An increasing focus on corporate governance will continue as boards need to be more astute fiduciaries in this tough economy,'' Blum added.

Quality of care concerns will certainly be one force putting pressure on corporate boards, Elisabeth Belmont said. ''If a health care provider is not delivering high quality care and the board knew or should have known about it, yet they did nothing while the institution continued to submit claims to Medicare and to other payers, then the hospital's leadership may be held responsible for quality fraud,'' she said.

Reece Hirsch and Michael Peregrine both pointed to recent litigation in state court that has exposed corporate boards and their general counsels to increased scrutiny and required them to defend their corporate oversight and compliance activities.

According to Hirsch, one case held that the general counsel of a health care staffing company had fiduciary duties that required affirmative action to protect the interests of the company. ''Given the current financial crisis, that holding is particularly significant for health care companies facing bankruptcy or derivative lawsuits,'' he added.

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The *Health Law Reporter* Editorial Advisory Board Looks Beyond 2009

Asked to predict the major issues facing health law attorneys and their clients over the next three to five years, board members listed medical tourism (including globalization of health care and telemedicine) and personalized medicine (including genomics and genetic research), but the topic cited most often was also the one heading our Top 10 list: health care reform. Board members see this occupying the nation and its lawmakers in 2009 and for several years thereafter.

Health Care Reform, Access. Bob Roth said that if broad reform is not enacted soon, debating it will dominate the next several years. ''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 46 million new insureds,'' he said.

Jack Rovner said the focus of current proposals is a public-private partnership much like the current one in which Medicare Parts A/B are provided by federal insurance and Medicare Advantage and the Part D prescription drug plan are the province of private insurers. In coming years this hybrid structure will present ''substantial business opportunities for the health insurance industry, or at least those who will embrace and prepare for the opportunities,'' Rovner said.

John Blum predicted that with increased financial pressure and more people out of work and lacking insurance, ''lower cost alternatives such as minute clinics staffed by nurse practitioners will become front-line providers, fanning ongoing disputes over scope of practice.'' Mark Waxman likewise said he sees the ability to provide medical advice in settings such as pharmacies and large retail stores driving the changing health care landscape.

Providers and educators increasingly will turn to telemedicine to ameliorate access problems, BNA was told. Domestically, a growing number of states, like New Mexico, will begin using ''telepsychiatry'' to connecting patients with mental health providers by video or by phone from the patient's via computer, or from a doctor's office or a community setting such as a health center or school.

Globalization of Health Care. The number of Americans going abroad each year for care could ''increase exponentially,'' Fred Entin predicted, stimulated by the same ease of travel, communication, and technologies that are giving worldwide scope to almost all industries. Also, evidence of the globalization of health care already is abundant, he said, citing the ability to digitize and transmit images that has led to the outsourcing of many radiology procedures and the proliferation of affiliations between academic medical centers in the United States and providers in other countries.

Katherine Benesch said the use of electronic systems in patient care and specialty consultation for diagnosis and treatment allows providers and health care institutions to enlist the skills of expensive physicians in specialties like radiology, cardiology, and neurology, without paying them to be on-site and available at all times. As medicine increasingly involves review and interpretation of electronic test data, telemedicine will become more and more important as a way to offer patients care through their own physicians but with the skilled technical backup those physicians need to provide quality care at reduced cost, Benesch said.

Doug Hastings said that as with other industries, ''there is no reason that health care products and services will not become increasingly available globally with all of the consequent transactional, regulatory, and litigation issues that will follow.'' Entin agreed, saying legal issues globalization will create for health lawyers ''will be many and exceedingly complex, including medical liability, licensure, privacy, credentialing and accreditation, ERISA, and tax and insurance regulation.'' Also, becoming more prominent, Entin said, is the expectation that U.S. employer health benefit programs eventually will incorporate options to receive care abroad as a cost control measure.

Personalized Medicine, Genomic Research. Finally, several board members selected personalized medicine—using genomics to develop therapies tailored to an individual patient—as a key issue on the near horizon.

Elisabeth Belmont said she expects personalized medicine to receive a boost from the incoming administration since, as a senator, Obama introduced legislation to provide more support for private research and to coordinate sometimes conflicting federal policies. Obama also proposed a 100 percent tax credit for research to develop diagnostic tests to predict the safety and effectiveness of certain high-profile drugs, she said.

Addressing the genetic research required for personalizing treatments, Belmont cited some of the upcoming legal issues: 1) should physicians have the right (or obligation) to warn close relatives of a patient they might have a significant risk of carrying a gene that could seriously endanger their health or the health of potential children if the patient refuses to do so? 2) will providers face malpractice lawsuits if they fail to inform patients of any background risks and the availability of relevant genetic tests? 3) will ''genetic malpractice actions'' allege physicians did not tailor therapy to appropriate analysis of the patient's genotype?

When personalized medicine does come on line, it ''will change everything,'' Richard Raskin said. ''It will fundamentally change what we are able to know about ourselves as patients, how laboratories screen patients, how that information is stored and shared with other providers, and how it is used for the benefit of the individual patient and for all patients. It will change how manufacturers develop new products, and also how they structure their businesses. It will drive changes in medical education and will likely require a restructuring of the payment paradigm.''

"Clearly, the IRS' interest in corporate governance will only grow sharper and more intense, and executive and board leadership will be expected to respond accordingly."

MICHAEL W. PEREGRINE, MCDERMOTT WILL & EMERY, CHICAGO

Peregrine also pointed to another source of ongoing governance pressure, citing Internal Revenue Service initiatives to obtain information about oversight by nonprofit boards of a range of tax law compliance issues involving compensation, conflicts of interest, joint ventures and other areas.

''Recent speeches by senior IRS officials make it very clear that the agency will continue its initiative with respect to corporate governance. This will be manifested in part by review of submitted answers to Part VI of the revised Form 990, by the insistence of the IRS that tax-exempt organizations remain, according to Commissioner Douglas Shulman, 'squeaky clean,' and by its paying particular attention to suspect activities and transactions during the current economic turmoil,'' Peregrine said.

''Clearly, the IRS's interest in corporate governance will only grow sharper and more intense, and executive and board leadership will be expected to respond accordingly,'' he added.

Peregrine said he also expects that the IRS focus on governance generally, and through Part VI of the Form 990 in particular, will manifest itself in the form of ''increased attention to the potential for bias in the decision making process at the board level—whether it relates to independence of board members, 'horizontal' relationships between board members, or transactions with 'interested persons,' and whether directors are 'disinterested' for purposes of the rebuttable presumption of reasonableness under Section 4958 and adequately guarding against traditional conflicts of interest.''

Sullivan agreed. ''Implementation of the new IRS form 990 with its focus on governance and compensation is leading—some might say dragging—all charitable organizations to tighten up their governance policies, especially those involving approval and reporting of compensation they pay,'' he said.

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