Lead Report

Outlook 2007

Fraud and Abuse Again Takes Top Spot Among Health Law Issues for Coming Year

Fraud and abuse is ''still the one,'' according to an informal survey of members of *BNA's Health Law Reporter*'s editorial advisory board, who were asked to rank the key issues for health care providers in the coming year.

Like last year, fraud and abuse ranked first in *HLR*'s annual ''Top 10'' survey of advisory board members. For 2007, health information technology and taxation placed second and third, followed by Medicare, quality of care, antitrust, Medicaid, labor and employment, health plan regulation, and corporate governance. Three issues receiving honorable mention this year are medical staff, coverage of the uninsured, and professional liability.

Still, fraud and abuse is the body of law the majority of health lawyers work with most of the time, in large part because compliance issues are so interrelated that solutions to comply in any one area have implications for several others, attorneys said.

Fredric J. Entin of Foley & Lardner in Chicago summed up the comments of most board members when he said that the continuing evolution of this highly regulated industry is causing many who have been practicing in the health care field for some time to morph into new ''experts'' or at least develop new expertise.

MaineHealth's corporate counsel, Elisabeth Belmont in Portland, Maine, said attorneys specializing in the Stark self-referral and Medicare/Medicaid antikickback laws, for example, find themselves assisting in the development and implementation of sales and marketing compliance programs for pharmaceutical, biotechnology and device companies, or defending drug and device manufacturers subject to whistleblower actions under the civil False Claims Act, she said.

Meanwhile, those specializing in reimbursement matters are adding clinical trials and Medicare Part D prescription drug billing to their compliance concerns and specialists in FDA regulation find themselves addressing the appropriate classification of emerging biotechnology products, Belmont continued. In addition, transaction specialists are assisting in negotiating and structuring strategic joint ventures between and among life sciences companies, academic medical centers and community and regional hospitals, and private funding sources; and health care attorneys with venture capital and hedge fund expertise are helping clients identify and deal with emerging technologies, she added.

''To make it more interesting, in some areas the traditionally separate areas of health policy and health law are converging and scientific and technological advances in the health care industry are raising novel legal issues. Through all this change, the challenge for health care lawyers will be to make sure those implications are spotted and addressed. It is their job to look at issues for their clients without losing sight of the effect that advice may have on broad legal compliance,'' Belmont concluded.

Following are the issues expected to rank highest among their concerns for 2007.

1. Fraud and Abuse. Predictions are that 2007 will see health care providers, health plans, and their attorneys spending even more time on fraud and abuse law. ''No let up in this arena,'' the ''commanding presence in health care,'' and ''still the one'' were some of the comments BNA received.

Health Law Reporter's Top 10 for 2007

Advisory board members ranked these the most important health law issues for 2007:

1. **Fraud and abuse** takes the top spot as attorneys' primary concern.
2. Moving near the top is **health information** as the push for electronic medical records contends with funding and security dilemmas.
3. **Taxation/charity care** present issues of executive compensation, community benefit, and billing fairness to both exempt and for-profit health care organizations.
4. **Medicare** promises to be a major concern as politicians gear up for the 2008 election and Medicare Part D hands enforcers another target.
5. **Quality of care,** its definition, and its financial implications dominate the patient care debate as pay-for-performance, though not a slam dunk for adoption, becomes ''white hot.''
6. Enforcement of **antitrust** laws continues as the government and rivals scrutinizes hospitals and managed care organizations seeking partners with which to consolidate.
7. **Medicaid** will become a fertile source for whistleblower actions as a direct result of the Deficit Reduction Act.
8. Union campaigns and initiatives will make **labor and employment** a big issue as workers seek to expose inequities and alleged quality of care deficiencies.
9. **Health plan regulation** remains important as private payers seek to create transparency in price and quality and consumer-directed insurance grows.
10. Efforts undertaken to comply with a changing **corporate governance** landscape continue to consume the energy of health care entities and their boards.

Fraud and abuse continues to be ''the most pervasive and threatening area of liability for health care providers and companies,'' according to Richard D. Raskin with Sidley Austin LLP in Chicago.

It is ''the body of law that 75 percent of all health lawyers work with 75 percent of the time,'' Thomas Wm. Mayo, with Southern Methodist University, Dedman School of Law, in Dallas said. Moreover, Kirk J. Nahra with Wiley Rein & Fielding LLC in Washington, said health care fraud is an area where virtually every company in the health care industry can face significant threats, both for the company at large and individual employees.

This area, however, is evolving and in a new and unhealthy way, according to Robert L. Roth with Crowell & Moring LLP in Washington. Roth told BNA he sees policymakers becoming ''more and more enamored with using enforcement agencies to bring about dramatic results quickly through the use of FCA and criminal prosecutions.'' As a result, he said, the government is likely to continue to lower the threshold of what constitutes criminality in health care and reimbursement, raising provider/payer fears of seemingly arbitrary government actions.

What started a decade ago, when certain U.S. Attorneys began using the FCA to enforce quality standards in nursing homes, has led to the ''perceived displacement of compliance guidance and decision-making by regulatory agencies such as the Centers for Medicare & Medicaid Services and state health departments by criminal and highly-punitive FCA enforcement actions by the Department of Justice, Medicaid Fraud Control Units, and, by extension, the qui tam bar,'' Roth said.

This ''unhelpful'' development will be the single most significant issue defining the health care system for the next several years, he said. It is a problem because enforcement agencies, due to ''their narrow focus, do not approach compliance issues ''with the same nuance and calibration as the regulatory agencies.'' Instead, Roth said, they tend ''to characterize certain behaviors as 'legal' or 'illegal,' rather than evaluating them across a continuum,'' and so they often do not discriminate adequately between the egregious and the inoffensive. The result is a ''siege mentality'' in providers and payers who can find the government ascribing ''a malevolent intent to actions that are motivated, not by malice, but by the need to manage costs without compromising quality.''

Katherine Benesch with Duane Morris LLP in Princeton, N.J., expressed similar concerns. The federal and state governments ''seem to be spending more and more time and effort trying to catch providers in this web of diffuse, difficult, and ever-changing regulations,'' she said, adding that some prosecutors even appear to be ''using the threat of criminal sanctions against health care providers to garner extensive and ongoing publicity.''

Nahra, however, said it is not clear the government sees fraud and abuse enforcement as a way to make policy, at least not in every arena. ''We've seen the criminal enforcement system sit back in some areas, such as in Health Insurance Portability and Accountability Act enforcement,'' he told BNA, ''where only a handful of very egregious cases have been prosecuted. We've also seen government defeats in some of these 'policy' cases.''

''We'll just have to watch what the government does in certain new areas, such as Medicare Part D, where there are enormous operational challenges, and where aggressive government enforcement could threaten the viability of the entire program,'' Nahra said. ''Health plans now face new compliance risks, tied to both Medicare Part D benefits and the Medicare contracting process. These are areas where prosecutors and others are looking actively to make cases, and where whistleblowers may see some new opportunities,'' he said.

Sandy Teplitzky, with the Baltimore firm of Ober, Kaler, Grimes & Shriver, agreed, saying ''long-standing OIG investigations regarding the manufacture, distribution, and sale of pharmaceutical drugs may well come to fruition this year.''

Jack A. Rovner of Neal, Gerber & Eisenberg LLP in Chicago, noted that Medicare Part D becomes a year old in 2007 and that, effective Jan. 1, Part D plan sponsors should have had their fraud, waste, and abuse prevention, detection, and correction programs up and running. Furthermore, the first-round financial reconciliation for the 2006 plan year will take place over the next six months. That process alone, plus political pressure about the expense and benefits of a private-plan model, is likely to stimulate intense fraud and abuse investigation and audits, he said.

''No let up in this arena,'' the ''commanding presence in health care,'' and ''still the one'' were some of the comments BNA received about fraud and abuse issues.

In Raskin's view, a more basic reason that the numbers of enforcement actions against providers will grow is that applying CMS medical coding and reimbursement guidance to real-life clinical situations necessarily involves the exercise of judgment and the possibility of differing viewpoints. Government enforcers and qui tam plaintiffs, who have strong incentives to identify areas in which providers may have exposure, zero in on these ambiguities, he said.

Toby Singer with Jones Day in Washington identified physician/hospital relationships as fertile ground for new cases, particularly for FCA whistleblowers. Entin agreed, saying that, with hospitals' increasing competition for clinicians, he expects in 2007 to see an enforcement focus on physician recruitment and retention agreements.

According to Howard Burde with Blank Rome LLP in Philadelphia, another reason to anticipate more enforcement activity in the general area of hospital/physician relationships is that, with Rep. Pete Stark (D-Calif.) chairing the House Ways and Means Health Subcommittee, there is likely to be a push to expand the reach of both the anti-kickback law and the physician self-referral law that bears his name.

Hospitals have good reason to ''tremble at the mention of Stark's name,'' T.J. Sullivan with Drinker Biddle & Reath LLP in Washington remarked.

Because any regulatory ambiguity is fertile ground for enforcers, several attorneys said they eagerly are

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anticipating the publication of CMS's Stark II Phase III regulations, which Teplitzky predicts will come out no later than March. Most of these attorneys questioned the utility, in their present form, of the new anti-kickback safe harbors and Stark law exceptions relating to electronic technology donation and sharing and said they hope CMS will provide better compliance guidance in the Phase III rulemaking.

Teplitzky said better guidance also is needed under the Stark exception for academic medical centers and that questions also have been raised over the past year regarding the development of joint ventures to provide equipment and management services to entities providing designated health services. ''In fact, the Medicare Payment Advisory Commission has recommended that the definition of a designated health service entity be expanded to cover leasing and management joint ventures, which have been viewed by some as an 'end run' around the prohibition of physician ownership of entities that provide, and bill for, DHS,'' he said.

As in the past, significant questions also remain as to the appropriate treatment of ''de minimus'' or ''technical'' violations of the Stark law, where a literal application of the nonpayment provision of the law would far exceed the ''harm'' to the government, for example, where an agreement meets all of the elements of the exception, except that one of the parties failed to sign the agreement, Teplitzky said. He also said he sees the possibility of congressional action if CMS's Phase III regulations fail adequately to address these issues, which ''desperately need attention.'' Reece Hirsch of Sonnenschein Nath & Rosenthal LLP in San Francisco said he hopes that issuing the Stark regulations ''will free up resources at CMS to devote to the stalled Stark advisory opinion process.''

Teplitzky said he also expects the HHS Office of Inspector General will continue to exercise its ability to bring civil money penalty cases under the federal anti-kickback statute and the Stark law, even when they are cases DOJ chooses not to pursue. The numbers of these cases will grow because they ''allow the OIG to express and pursue its views of various arrangements and transactions under those statutes while using a lower burden of proof than would be required in a criminal action brought under the anti-kickback statute,'' he said.

One enforcement bright spot is the ''McNulty Memo,'' DOJ's Dec. 12, 2006, revision of its policy governing corporate prosecutions, which appears to recognize that government ''moderation in the pursuit of wrongdoing is itself a positive value,'' Roth said. This may be the ''start of significant discussion about the use of government power to punish health care providers,'' he added.

Benesch, too, said the McNulty Memo is ''particularly important for health care corporations, providers and health lawyers, as the health care industry is one of the largest sources of whistleblower and FCA lawsuits today.''

Nahra agreed the McNulty memo is significant, but said many are overstating its real impact. ''Companies were never going to be prosecuted simply because they wouldn't waive privilege. The McNulty Memo simply alters the overall enforcement dynamic somewhat. Because the government looks very aggressively at corporate management's involvement in large-scale health care fraud schemes, however, corporations still face significant risks of prosecution—or credible threats to prosecute—even without the pressure on privilege waivers.''

With the passage of the Deficit Reduction Act, Medicaid also promises to prove fertile ground for fraud and abuse litigation (see Medicaid section below).

2. Health Information Technology. Board members told BNA that in 2007, as J. Mark Waxman, with Foley & Lardner in Boston, put it, ''the entire HIT area will become both more important and more complex at the same time.''

Belmont in Portland, Maine, said that in signing Executive Order 13410, ''Promoting Quality and Efficient Healthcare in Federal Government Administered or Sponsored Healthcare Programs,'' last August, President Bush furthered the federal push toward interoperable electronic health records (EHRs) and promoted the transparency of both quality and price data in purchasing health care.

''The entire HIT area will become both more important and more complex at the same time.''

J. MARK WAXMAN,
FOLEY & LARDNER, BOSTON

''By May 23, all HIPAA-covered entity providers should have national provider identifiers that will enable developers of transparency tools based on administrative (e.g., claims) data to profile specific providers,'' she said. The E.O., coupled with new anti-kickback safe harbors for technology donation and sharing, likely will encourage increased HIT acquisition and the development of networks sharing patient information between providers and payers, she said.

Burde predicted 2007 will be the ''the year that personal health records (PHRs) become the centerpiece.'' All these developments will create numerous challenges for health law attorneys in the coming year, he added.

Nahra agreed that this year will be a crucial one for electronic records. ''We're seeing a perfect storm of forces pushing for more uses of technology—from the administration, health care businesses, payers, employers and consumers. The challenge will be to see if a regulatory structure can keep pace with the marketplace.'' Nahra, who co-chairs the newly formed Confidentiality, Privacy and Security Workgroup, a panel of government and private sector privacy and security experts advising the American Health Information Community (AHIC), also said, ''We're going to see privacy and security as a critical component of this ongoing evolution. While increased privacy and security controls may reduce the administrative efficiencies of the market, these programs will not succeed without consumer trust. Our challenge is to draw the right balance.''

Rovner said payers' introduction of PHRs will be accompanied by significant technological developments and that 2007 will see ''other players, both within and without the health care industry, pursuing the business opportunities and innovations needed to bring interoperable, secure, effective technology to the goal of an electronic health record and a national health informa-

tion infrastructure.'' Physicians, however, will continue to lag behind, he said.

Hirsch sees the recent announcement of PHR programs by five major employers (Applied Materials, BP America, Intel, Pitney Bowes, and Wal-Mart) as ''a major test for the PHR concept. As the industry struggles with full EHR implementation, PHRs could prove to be a significant first step down that road,'' he said.

Burde said he expects the Democratic Congress to force health plans to provide PHRs to their members, adding that ''the focus on PHRs rather than interoperability will cost less and allow Congress to avoid nasty fights over privacy.''

Congress may avoid dealing with health records privacy, but to judge from other lawyers' comments, it will be the only one doing so.

Entin said more systems and more data likely will lead to renewed concerns about privacy and security, especially if there is a highly public incident of breach. Hirsch predicted that ''the passage of state security breach notification laws in recent years, combined with the proliferation of identity theft and large electronic databases of patient information, will be a recipe for privacy and security litigation.'' High-profile security breaches in the health care industry, and related lawsuits and state regulatory action, will increase the pressure on CMS to take a more aggressive approach to HIPAA enforcement, he said.

Mark A. Kadzielski with Fulbright & Jaworski LLP in Los Angeles also predicted HIPAA enforcement will begin in earnest in 2007, adding that, when it does, ''it will be felt throughout the health care industry.'' Rovner sees attorneys being forced to deal with ''the intersection of HIPAA effectiveness and individualized state privacy laws.''

Belmont said she sees significant confidentiality issues stemming from the growth of health care infomediaries that will emerge to capture and analyze the aggregate patient data providers and health plans increasingly will use for profiling and proprietary purposes. For the same reason, she sees proprietary rights issues becoming increasingly important in 2007.

Unfortunately, she added, medical identify theft will be another result of the growth in EHR and records sharing. This kind of theft is on the rise and especially difficult for consumers to detect. Providers will have to devote all necessary resources ''to ensure they are utilizing appropriate administrative, physical and technological safeguards to maintain EHR confidentiality and integrity,'' Belmont said.

But Sullivan said HIPAA compliance already is consuming significant provider resources. Waxman sees the statute ''coming into its own as much more than simply 'Let's keep medical records private.' '' IT issues come up daily as information becomes more and more important to delivering and paying for quality, he said.

Nahra said many of the largest problems are coming from entities at the periphery of HIPAA regulation. ''We're seeing problems with a wide variety of vendors, who may have business associate contract obligations, but typically are not subject to HHS enforcement. Also, lots of the new entities participating in the PHR market aren't covered in any way by HIPAA.''

The move toward IT adoption will reveal a ''raft of other legal issues yet to be resolved,'' Entin said. ''Ambiguities and unanswered questions in the new safe harbors and Stark exceptions for electronic prescribing and donation of HIT will have to be addressed. Antitrust allegations also may arise as the motivations of some organizations are challenged,'' he said.

Entin said some organizations will move forward very cautiously with plans to acquire technology because of both compliance guidance ambiguities and reports of problems at other hospitals. One example, according to Entin, involved Kaiser Permanente, where, according to news reports, an internal memo sent by a concerned employee warned the health maintenance organization could lose as much as $7 billion over the next two years because of allegedly ''inefficient and ineffective'' IT spending.

''Too often technology acquisition is treated differently than other business transactions in the health care field,'' Entin said. ''IT is too often seen as a technical exercise with much early discretion delegated to IT professionals without the input of lawyers. Without the early and consistent advice of counsel experienced with the acquisition of such expensive technology, frustration with results of implementation may not be adequately addressed. What often is not acknowledged until too late is that contractually the purchaser has the best chance of obtaining meaningful warranties and remedies when legal counsel is involved as early as the request for proposal,'' he said.

Entin expressed other HIT concerns. Providers, government, insurers, and employers all may recognize that effective use of technology is the key to the two universal goals of improving health care quality and reducing costs, he told BNA, but those committed to moving ahead ''will find only token financial support from the government at a time when capital access for many non-profits remains tight.''

William A. Dombi, director of the Center for Health Care Law, in Washington, also sees funding problems ahead. However, he optimistically predicts that ''legislative and regulatory interest in technology related matters will grow including not only efforts to secure greater federal financing but also agency guidance specifically to address concerns regarding provider-sponsored technology for physicians.'' Roth, too, anticipates that a new Congress might mean it is ''time for action—read funding—in this area,'' while Sullivan would only state that legislation might be required to cover ''the enormous expense'' of implementing EHR and declined to predict the likelihood of this occurring.

Meanwhile, 2007 will see continuing experimentation with acceptable forms of regional information sharing through regional health information organizations (RHIOs) and employer-sponsored personal health records giving lawyers a myriad of issues to coordinate, board members said.

Hirsch cited the recently announced closure of the Santa Barbara County Care Data Exchange, a pioneering RHIO, as proof that no one should underestimate the difficulties in implementing RHIOs. ''Tough issues include making a business case for the costs associated with establishing and operating a RHIO and getting the participating providers comfortable with liability concerns associated with privacy and security issues,'' Hirsch said.

''In the coming year, it will be interesting to watch many of the new RHIOs move from the planning stage to implementation,'' he added.

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3. Taxation/Charity Care. In last year's ''Top 10,'' taxation and governance issues were paired because of the strong connection between the issues being scrutinized by the Internal Revenue Service and Congress and the evolving roles of corporate boards in ensuring compliance aimed at deflecting such oversight and attention. This year, board member comments lead to the conclusion that taxation should once again be paired, but this time with the charity care and hospital billing issues historically categorized as provider regulation.

According to Sullivan, ''the IRS, for its part, will not relinquish its bulldog focus on executive compensation, nor will the press likely ignore the clearer public disclosures now available as a result of the new Form 990 instructions.''

The IRS ''will continue to be overextended in comparison to its budgetary and staff resources, especially if funded only by a year-long continuing resolution, which will make it difficult to tackle the intricacies of emerging issues such as the tax implications of enterprise-level and regional-level electronic health record development.''

He said he expects the change in Congress to result in a shift away from a focus on achieving market conditions favorable to health savings accounts, which could mean less pressure for pricing transparency and discounts for the uninsured.

Douglas M. Mancino, with McDermott, Will & Emery in Los Angeles, said that, despite IRS resource limits, he expects executive compensation and intermediate sanctions reviews to remain significant issues for hospitals this year. ''The IRS plans to examine approximately 30 of the 540 hospitals that returned the IRS questionnaire and there are Team Examination Program audits just starting now,'' he said. ''Also, 'live' intermediate sanction audits of executive compensation of health systems are expected to continue,'' he added.

Howard T. Wall with Capella Healthcare Inc., Franklin, Tenn., predicted that the *Provena Covenant* property tax case, the application of emerging corporate governance principles, and congressional scrutiny and legislation concerning hospital billing and collection practices will continue to transform the face of traditional community tax-exempt hospitals.

Mayo said the overlap between tax, provider regulation, and governance issues will continue to be strong. ''The two end-of-year Congressional Budget Office reports on exempt hospitals are some evidence of how wary of the nonprofit sector even this nonpartisan organization has become,'' he said.

''If that is any indication of the breadth of feeling on the Hill, this might be the year we see an explicit charity-care requirement inserted into 501(c)(3),'' Mayo added. ''Even if that doesn't happen, the scrutiny of executive salaries, questionable business expenditures, uncompensated care, and billing and collecting practices will probably not let up one single bit.''

Eric Tuckman, with Advisory Health Management Group in Manhattan Beach, Calif., said the past few years have seen an unprecedented buildup of balance sheets for many of the larger health care systems, noting that ''successful hospitals have invested a significant portion of their assets in IT infrastructure development, yet enormous sums of cash remain under corporate control.''

He said the recent trend of demanding accountability regarding the disposition and use of these funds is likely to continue and that ''historical requirements regarding 'direct charity care' are likely, in the era of tightening budgets, to give way to increasing public influence over the utilization of a portion of 'excess' balance sheet assets for general public health purposes.''

Tuckman also predicted that a ''collision between the property interests of private corporations and the public accountability expectations associated with charitable trusts is likely and could result in creative 'settlements' to avoid litigation that could establish unwanted precedents.''

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

He agreed that the increased regulatory scrutiny concerning hospital billing and the provision of uncompensated care is an issue that will continue to resonate this year. ''The adoption of statutory standards for charity care and discounts akin to the approach adopted by California is likely to be repeated in those states that have not addressed the issue so far,'' he said.

''Charity care and discount policy will continue to serve as the lightning rod for drastic reform in the area of hospital billing,'' Tuckman added. ''The complexity and confusion associated with the current archaic and incomprehensible approach to hospital accounting will eventually lead to a consumer revolt and simplified billing at least for nongovernmental patients,'' he said.

Douglas A. Hastings of Epstein Becker & Green PC in Washington predicted ''tax-exempt health care organizations will continue to face a variety of critical challenges in 2007, including questions as to the fundamental basis for tax-exemption in health care, charity care requirements, executive compensation scrutiny, and conflict of interest concerns.''

Overall, he added, ''good governance and transparency remain essential elements in ensuring that tax-exempt entities meet their charitable obligations.''

John J. Durso, with Ungaretti & Harris in Chicago, said ''the times they are a changing, rather dramatically, when it comes to the traditional exemptions enjoyed by nonprofit health systems at the federal, state and local levels.'' With the community benefit standard under fire, he said, ''the question is becoming not just 'what have you done for your community?' but 'how much free and discounted care have you been able to provide?'

''Gone are the days when being a not-for-profit and delivering health care will carry the day with governmental reviewers. This issue has a momentum that will make for a 2007 replete with challenges to the status quo at every level of government,'' he concluded.

Sullivan said he believed the change in leadership in Congress should shift activity in this area to the states,

where ''a continued focus on standards for exemption in Illinois and other states could begin to change the landscape of exemption from the bottom up.''

John D. Blum, with Loyola University School of Law Institute for Health Law in Chicago, said that, while he believed the issues of charity care and community benefit may have cooled a bit, ''they will remain in the sights of state regulators.''

Michael W. Peregrine, with McDermott, Will & Emery, Chicago, said he expects the new SEC rules on disclosure of executive compensation, coupled with the revisions to the Form 990, to have a significant effect on health care organizations. ''This impact will be felt both in the degree to which compensation decisions will become transparent from the compensation committee to the board, and in the degree to which compensation decisions are reported to the IRS, state charity officials, and constituents,'' he said.

Another development in this area, Peregrine added, ''will be the increased pressure on compensation committees to confirm that they have taken into consideration all elements of compensation—including not only cash compensation but also such items as retirement benefits and expense assumptions—in determining compensation reasonableness.''

4. Medicare. Medicare remains a perennial Top 10 issue because of its sheer size and its effect on the health care industry as a whole. Many board members predicted small changes to the program in 2007, most notably to the Part D drug program, and forecast a growing debate on the future of Medicare, as political parties gear up for the 2008 election.

Number one on the health care agenda for the Democrat-controlled 110th Congress ''will be a new look at Medicare and in particular the Medicare Part D drug plan,'' according to Benesch.

Democratic leaders have said they favor legislation to amend the Medicare prescription drug program to allow the CMS to negotiate Part D drug prices and shrink the so-called doughnut hole in coverage.

Benesch said it was a ''mistake'' not to allow the federal government to negotiate drug prices with pharmaceutical companies on portions of the Part D program. It ''leads to a double-whammy for seniors and their families as drug prices are higher, and seniors pay more of their own money out of pocket for prescription drugs under Medicare Part D due to the 'doughnut-hole' aspect of the insurance,'' she said.

Sullivan said ''Republicans will argue strenuously that the new drug benefit plan is working and market forces should be allowed to play out.'' But, he added, ''don't count on'' Democrats letting that happen.

If such legislation does go through, however, ''look for drug costs to actually rise as a result,'' predicted Burde. ''Congress will seek to amend the drug benefit,'' he agreed, but they will do so despite the cost of the program being below original estimates.

Rovner questioned how government negotiations would work. Would CMS negotiate on behalf of private drug companies? he asked. And would private plans have to use those negotiated prices? ''If so,'' he said, ''what does that do to [drug plan] formularies?''

In the end, Rovner predicted little actual legislation ''given the make-up of Congress and the administration.'' Instead, there will be a lot of talk, hearings, committee reports, and press conferences, as the parties position themselves for the 2008 presidential election.

Tuckman, on the other hand, said ''the likelihood of further refinements and expansions to Part D is virtually a certainty in the coming year.'' He added that ''changes in the manner and scope of reimbursement for outpatient services is also very likely, in particular the scope of approved ambulatory surgery procedures and leveling the playing field regarding reimbursement paid for all outpatient services.''

Many board members told BNA that the leadership change in Congress also could bring a reexamination of the future of Medicare, with lawmakers debating whether quality and cost are better served by using private health plan contractors or the government-administered Medicare system.

Roth said, ''I see Congress debating the mega-issue of whether the future of Medicare is better served by the Republican vision of private health plan contractors or by the Democrat vision that 'original' Medicare is the safest way to go both with regard to quality and cost.'' The Part D program and the broad range of options available under Part C (Medicare Advantage) will figure prominently in the debate about the future of Medicare, he said.

Medicare Advantage—Medicare managed care—has brought ''so much creativity'' to the program in a relatively short period of time, Roth added. There also has been a lot of growth in the popularity of private fee for service plans offered under Medicare Advantage.

''It will be important to see the extent to which these programs are (1) embraced by beneficiaries, providers, and private payers, and (2) reduce the growth rate for Medicare costs,'' Roth said. ''I think it could be time for a spirited debate.''

According to Dombi, the 109th Congress also left ''much unfinished business related to Medicare physician payments.'' The ''antiquated Sustainable Growth Rate (SGR) system will be waiting for the new Congress throughout 2007,'' he said.

The SGR formula, which controls the degree of annual change in Medicare reimbursements to physicians, has resulted in required annual reductions in Medicare reimbursements for doctors for the past several years, Dombi said. Historically, Congress has dealt with the scheduled reductions by adopting one-year, ''stop-gap'' measures to prevent any decrease in Medicare physician payments.

Last year was no different, Dombi said, noting that, on Dec. 9, 2006, Congress passed the Tax Relief and Health Care Act, which included a one-year freeze for Medicare Physician payments for 2007, reversing the negative 5.0 percent payment rate update mandated by the SGR formula.

''This issue affects all provider groups, that is what makes it difficult,'' Dombi continued. More money to pay physicians means payment cuts in other areas, like home health care and nursing homes, he said. Doctors ''will make a strong push for systemic reforms'' to the SGR system, he said. But when push comes to shove at the end of 2007, Dombi said Congress likely will pass another one-year fix.

5. Quality of Care. Several board members ranked quality of care number one, among them Waxman, who predicted the meaning of quality and its financial impli-

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cations will dominate health care debate in the coming year.

Hastings, who is on the Institute of Medicine's board of health care services, was even more emphatic, calling quality ''the health care issue of the decade.'' Recognizing cost efficiency as a component of quality is a substantial advance on this front, he said.

''There has been great progress this past year in recognizing that efficiency is an element of quality—not just effectiveness of care, which people understood, not just the elimination of errors, which is critical and people also understand—but also cost efficiency specifically. The IOM said this in 2001 in 'Crossing the Quality Chasm,' but in my judgment it wasn't recognized by the legal/regulatory community,'' Hastings said. ''It now has been and that is real progress and will help allow for future aligning of incentives so providers can provide high quality and cost efficient care,'' he said. ''Quality and cost efficiency are not in opposition with each other. They more generally are consistent with each other.''

''Crossing the Quality Chasm'' described efficiency as using resources to get the best value for the money spent, as opposed to using resources without benefit to patients. Two ways to improve efficiency, the report said, are reducing quality waste and reducing administrative or production costs. Not all, but many types of quality improvements result in lower resource use, and this is true both for improvements in effectiveness that result from reductions in overuse and for most improvements in safety, which result in fewer injuries.

As a result, ''quality presents significant legal issues and important board fiduciary issues,'' Hastings told BNA. ''It has become a front burner issue both from a business and legal standpoint for virtually all health care providers and will remain so in the months and years ahead.''

Raskin said he expects more calls to tie reimbursement to quality this year, but said these initiatives must be accompanied by additional efforts to figure out how to do this and what quality means. This is the ''pay-for-performance'' aspect of the quality debate, he said.

''In 2007, Medicare expands hospital quality reporting requirements from 10 to 21 core measures, and extends the reporting requirements to physicians,'' Hirsch said. ''It will be interesting to see how consumers use, or don't use, the government's published hospital quality ratings,'' he added.

Also in 2007, Kadzielski said, stringent new medical error reporting laws will take effect in California, subjecting health care providers to significant fines for errors that put patients into ''immediate jeopardy.'' Private payers also have been pushing for proof of quality improvement and better ''performance'' in the quality area as part of the payment process, he said.

United Healthcare and other managed care entities have established P4P programs that provide financial incentives to providers for quality improvement while holding the line on payment for those who only maintain quality, he said. ''Indeed, providers who fail to improve quality may be at risk for having their contracts terminated because payers focused on rewarding improving providers may not have sufficient resources to continue paying marginally performing providers,'' Kadzielski warned.

Where enhanced payments for quality are available, he predicted increased emphasis on competent credentialing as a significant part of ensuring that only the best individual providers are part of the health care team.

Other payers will continue to be influenced by the health care quality monitoring of private, business-oriented groups such as the Leapfrog Group, composed of large corporations and public agencies that use their employer purchasing power to recognize and reward health care industry improvements in patient care safety, quality and customer value.

Kadzielski sees Leapfrog's annual Hospital Quality and Safety Survey, in which hospitals report on adherence to evidence-based quality and safety practices that reduce unnecessary deaths and injuries, continuing to be an industry standard.

''Quality and cost efficiency are not in opposition with each other. They more generally are consistent with each other.''

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

Waxman said he sees the financial implications of poor care quality becoming the lever for system change. ''If patients can and will legitimately not pay their bills when quality is substandard, and material amounts of payment are based upon delivering quality,'' change will happen, he said. ''As patients, we should be happy about this emphasis,'' Waxman added.

As a group, however, board members were less than sanguine about the likelihood of results. Like Raskin, Rovner sees the health care industry and the politicians continuing to search for effective ways to measure and reward quality care. ''I doubt we'll see much real progress, at least until there is more effective IT use in health care,'' he said. ''Effective IT, including the ability to correlate outcomes and costs; to monitor necessity, let alone quality, of care; to run better analyses—basically, simply ensuring that care-givers have ready access to better data and information—instantly at the point of care, is probably what is needed to transform health care delivery to a quality-based platform,'' Rovner said.

Peter N. Grant, with Davis Wright Tremaine LLP in Seattle, agreed that the P4P issue is ''white hot'' but reminded readers that two key House Democrats, Stark and Rep. Henry Waxman (D-Calif.), have questions about its adoption. Dombi, too, said that CMS may be starting P4P demonstration projects, but pointed out that Congress is signaling ''its future is far from certain.''

Roth also said quality issues will remain ''highly visible in rhetoric'' about transparency and about the market's ability to reduce costs while increasing quality performance. However, typically there is ''much more talk than action on quality and 2007 won't be any different,'' he said.

Hirsch said, ''P4P goes hand-in-hand with the trend towards pricing transparency,'' which continues to gather momentum. He said that the majority of states have passed some form of transparency requirement and that the federal Health Care Price Transparency

Act of 2006 could pass in 2007. Sarbanes-Oxley Act caused for-profit companies to focus on transparency issues, he said, ''Now a similar initiative seems to be taking hold in the nonprofit hospital sector.''

6. Antitrust. A perennial Top 10 subject, antitrust issues will remain a prominent component of the health law spectrum because of both public and private antitrust law enforcement efforts in 2007, advisory board members told BNA.

Robert E. Bloch of Mayer, Brown, Rowe & Maw LLP in Washington, said he expects the Federal Trade Commission and Justice Department to continue to be ''very active'' on the enforcement front, with the two antitrust agencies looking closely at hospital and managed care organization mergers and collusion among health care providers. ''The agencies have a strong interest in identifying price fixing by providers and the FTC, for its part, has had a long, successful track record in this area,'' Bloch said.

He also said he expects the agencies to continue to review and challenge hospital mergers, noting that the FTC in particular has looked closely at mergers by leading ancillary service providers. For example, the FTC recently investigated and challenged two multi-billion dollar mergers in the dialysis industry, Bloch said, adding that he expects to see more of these types of investigations.

On the private litigation side, Bloch noted the series of recently filed class actions alleging wage suppression of nurses' salaries by certain hospitals in Albany, N.Y.; Chicago; Detroit; Memphis, Tenn.; and San Antonio, Texas. ''These are unusual cases—not your usual price-fixing cases,'' Bloch said.

''In a service industry like health care with a great deal of competition among hospitals to recruit nurses and substantial diversity of individual skill levels, specialties and experience among nurses, it would seem to make class action treatment questionable,'' he added.

Raskin said he expects a continued emphasis on private litigation involving issues of supposed market dominance. ''Again, the pharmaceutical and medical device sectors will be particularly busy,'' he said.

''I also expect to see a continued flow of private cases involving exclusive contracting and access to managed care networks,'' he said. ''The issue of health plan dominance may also make its way onto the agenda,'' he added.

Entin said that antitrust remains important because, as the hospital field deals with issues of efficiency, consolidation in the form of mergers or acquisitions will be an option for consideration. He noted the FTC victory in a post-merger case, *Evanston Northwestern Healthcare*, ''after many years of failure in the court'' and said the ''final decision at the FTC level and then in the courts, on appeal, will be closely watched.''

Singer agreed, saying that the FTC staff ''is emboldened by its initial victory in the Evanston Northwestern hospital merger case'' and that she expects a decision from the full commission this year. ''They have already started looking more closely at proposed mergers and acquisitions,'' she added.

On the private side, she said, ongoing litigation, including class actions such as the nurse wage lawsuits, ''demonstrates that plaintiffs' class action lawyers have discovered the hospital industry.''

7. Medicaid. Few areas represent the increasingly intertwined nature of today's health care system like Medicaid, several board members said. As program costs continue their upward climb, they predicted that state and federal governments will look to increased fraud investigation and enforcement as well as experimentation with managed care programs and universal health coverage to help control spending.

''State and federal budget pressures will continue to create efforts to come up with creative solutions to the spiraling costs of Medicaid,'' according to Roth. And Medicaid enforcement will ''be one of the most dynamic issues of the year,'' he added.

Waxman predicted continued Medicaid experimentation through waivers, which allow states flexibility in operating their Medicaid programs.

One experiment everyone is watching is in Massachusetts where Gov. Mitt Romney (R) signed legislation requiring all state residents to obtain health insurance by July 1, 2007. The law envisions that approximately 100,000 individuals will be added to the state's Medicaid program, 200,000 low-income residents will sign up for state-subsidized health insurance, and another 200,000 will purchase low-cost policies on a pretax basis in the private market.

Waxman, however, cautioned that the Massachusetts program is brand new and that many concerns remain about its commercial viability. ''I doubt it is a one size fits all'' fix, he concluded.

According Benesch, ''Medicaid managed care seems to be a program of choice for state governments, as long as the managed care companies keep the costs down.'' There is particular concern for uninsured children and the elderly, many of whom fall within the Medicaid guidelines, she said.

Waxman said states may well look to fraud investigation and enforcement to provide revenue for funding Medicaid programs. ''States are looking to Medicaid fraud investigation and enforcement for many reasons,'' he said. ''While fraud is certainly bad, it's also a revenue source.''

In Dombi's view, states are likely to adopt their own false claims statutes. He cited the Deficit Reduction Act of 2005 and its provisions addressing Medicaid fraud and encouraging enforcement. While most FCA cases will focus on Medicare, Dombi said the DRA will ''open up the door'' for greater Medicaid enforcement as well.

Teplitzky said this is both good news and bad news for the industry. States' increased cooperation with federal authorities will lead to more global settlements and help avoid multiple investigations and prosecutions by individual states. At the same time, however, it will ensure that numerous states will participate in the process, even in situations where they otherwise would not, on their own, deem the conduct at issue to be worth pursuing.

Further, acting as a group, federal and state authorities will be less likely to consider the individual aspects of state statutes and regulatory schemes, which often cover different types of conduct and in many instances are inconsistent with one another. ''Providers, in my view, will lose the ability to argue that certain states could not have recovered under their own statutes, but rather, will be led into more general settlement discussions in an effort to resolve any potential exposure,'' Teplitzky said.

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8. Labor and Employment. Nearly all board members cited labor and employment issues on their Top 10 list, recognizing the effect union campaigns and initiatives throughout the country have had on the health care system. They include the exposure of alleged charity care and billing inequities, claimed quality of care problems, and wage disparity and price-fixing charges.

''Labor union corporate campaigns continue to create a difficult environment for not-for-profit hospitals and the stand-off is unlikely to ease any time in the near future,'' said Sullivan.

Singer agreed that union activity will increase. The Service Employees International Union and others ''will continue to mount corporate campaigns and spread their activities beyond the traditional labor arena,'' she said.

According to Entin, labor and employment is one area in which many of the issues come together. There will be ''especially aggressive utilization of the corporate campaign tactics used by unions like SEIU, the American Federation of State, County and Municipal Employees, and the nurses unions in several states,'' he said, adding that the corporate campaigns often involve ''questions about billing and collections, the merit of tax exemption, executive compensation, safety and mandated nurse staffing ratios.''

Unions in some localities are in direct competition for membership, he added, especially when it comes to organizing nurses. ''The pressure that such campaigns exert on their targets has not been abated sufficiently to discourage more of the same in the coming year,'' he said.

Waxman said hospital boards will need to educate themselves on all these issues because many boards have little experience with these corporate campaigns. There must be discussion, education, and training among those running hospitals so they can be advised on their options and decide what approach to take on matters like work rules, wage rates, competitive environment, and other issues that lead to unionization.

''How the industry addresses this renewed attempt at unionization may indicate the fate of many facets of the hospital industry,'' Waxman said. ''In the aggregate, it is likely that the unions will have some successes. But it is hard to predict.''

The impact of successful union campaigns likely will mean higher costs for providers, ''because unions' major goals are wages and benefits,'' said Dombi. Increased wages also could lead to higher costs for third-party payers like Medicare and Medicaid, he said, noting that the SEIU has stated that this is an issue involving labor, management, and the third-party payer.

9. Health Plan Regulation. Health plan regulation also received many votes from advisory board members who see the provision of health insurance and pharmaceutical benefits as an important component in the short-term evolution of the health care system. From interactions with pharmaceutical manufacturers and providers, to development of standardized protocols and technologies, to proposals for covering the uninsured population, health plans, they said, affect many parts of the health care system.

Stephanie W. Kanwit, special counsel for America's Health Insurance Plans in Washington, said she expects continued efforts by health insurance plans to improve health care quality and achieve greater transparency. These efforts include working in the area of performance measurement and reporting, pushing for e-prescribing and the adoption of evidence-based medicine, and developing interoperable health information technology, she said.

''Everyone talks about 'transparency,' but when health plans use the term they are talking about both price and quality.'' Health insurers are ''making a big push to ensure health care consumers have access to more information on the value of care they will receive from different providers,'' Kanwit said.

There are a series of governance issues ''all flying right now 'under the radar,' that could have a significant impact in 2007.''

MICHAEL W. PEREGRINE,
MCDERMOTT, WILL & EMERY, CHICAGO

''In the end, transparency relates to the provision of all and any information that will be useful to consumers and that maximizes safety, efficiency, consumer satisfaction, and access to the highest quality health care,'' she added

Belmont said she sees certain industry trends—including insurance premium increases; emergence of high deductible health plans with consumer decision support tools; and policy analysis on the quality, consistency, and safety of health care services—converging to make consumerism both a policy issue and a market force in health care.

Rovner predicted that continued evolution of the law of preemption under the Employee Retirement Income Security Act versus state-insurance regulation, as well as cost pressures on employer-based health benefits, will ''put pressure on plan/provider relations and plan/enrollee relations.''

Blum agreed that there probably will be continued pressure in the ERISA preemption arena, but said it will be a difficult area for plaintiffs, given the Supreme Court's ruling in *Aetna Health Inc. v. Davila,* 124 S. Ct. 2488 (2004).

Raskin said he expected continued growth in consumer-directed health insurance plans which could, in due course, lead to calls for its regulation.

10. Governance. Most board members also cited governance concerns as being of significant importance in most health care organizations, whether for-profit or exempt in corporate form.

Peregrine cited a series of governance issues ''all flying right now 'under the radar,' that could have a significant impact in 2007.'' The first is whether governing boards are truly responsive to their obligations to provide active oversight of the health care organization's compliance plan—from both organizational and operational perspectives, he said.

''The concern here is that some boards may have so delegated that responsibility that at the full board level they lack the information necessary to fully evaluate the legal and compliance risk profile of the organization,'' he said. ''Of related importance, is the role of the board

The *Health Law Reporter* Editorial Advisory Board Looks Beyond 2007

Advisory board members make the following predictions about the next three to five years.

Capitol Hill. Health care is near the top of the Hill's ''to do'' list, with the Democrats in control of Congress and the Republicans increasingly willing to distance themselves from the administration and formulate a winning health care plank for their 2008 presidential contender, board members say. But how much Congress will accomplish is a very open question, given the contentious nature of many health care issues and the Democrats' lack veto-proof majorities in both houses. Expect to see ''strange alliances'' and ''lots of wild cards on Capitol Hill,'' according to Thomas Wm. Mayo, with Southern Methodist University, Dedman School of Law, in Dallas.

Fraud and Abuse: 180-Degree Turn? Two fraud and abuse policy issues are likely to be addressed in the next few years, according to Eric Tuckman, with Advisory Health Management Group in Manhattan Beach, Calif. First is the appropriateness of the increasing prevalence of physician ownership of acute-care hospitals. Given the increasing influence of Rep. Pete Stark, a reexamination of the ''whole hospital exemption'' relative to physician ownership is likely, he said.

Second, Tuckman predicts, the thrust of existing federal regulation is likely to ''take a 180-degree turn.'' Current reimbursement paradigms reward providers who limit services under fixed-fee arrangements and have government enforcers ferreting out unnecessary utilization. Tuckman foresees enforcement switching to target practices that limit access to necessary services. Managed care companies' increased use of DRG methodologies also may tempt some providers to deny necessary services in an attempt to reap financial gains. ''The evolution of current payment systems will force regulators to change their emphasis and venture into the murky waters of determining clinical appropriateness,'' he says.

As the OIG further establishes how to voluntary disclosures, Sandy Teplitzky, with Ober, Kaler, Grimes & Shriver in Baltimore, said, he predicts providers increasingly will turn to the OIG's disclosure protocol in Stark and anti-kickback cases in the hope compliance problems can be resolved in a way that puts the matter behind them without requiring payments that might risk their very viability.

Health IT. ''It may seem like the coming revolution in health care information is something we only talk about but will never come to pass, like the Y2K catastrophe,'' Richard D. Raskin with Sidley Austin LLP in Chicago, said. ''But I firmly believe these changes are coming soon and will transform the way health care is delivered—in much the same way information technology has transformed other industries—leading to new issues in fraud and abuse, antitrust, and health plan and provider regulation. This is the issue that will have the greatest impact on the industry over the next three to five years,'' he said.

Board members also agreed that the administration will push ahead with HIT implementation even as HHS Secretary Mike Leavitt tries to bring U.S. employers on board with his ''four cornerstones'' plan. This plan calls on companies to use four criteria in purchasing health insurance with the primary criterion being interoperable health care IT. More information is available at http://www.hhs.gov/transparency.

Privacy and Security. The movement to health care IT also may have broader implications for privacy and security. ''I think that the progress toward more health care information technology will have the effect of revitalizing the American debate about how health care information can be used and must be protected,'' said Kirk J. Nahra with Wiley Rein & Fielding LLC in Washington. For this technology to be useful to control costs and improve medical results, ''the records must be complete, accurate and easily accessible. But this completeness and accessibility raises a panoply of privacy and security issues, which will drive both how useful electronic records will be and how accepted they will be by the American consumer. This information also can be used for numerous appropriate purposes, such as research, but only if the right protections are in place. I foresee a really active debate on what the privacy rules should be in this new environment.''

Stem Cell Research. Members of both parties have raised the subject of stem cell research, board members noted, and while the Democratic Congress will revisit funding for stem cell research, and will offer legislation that is more expansive than the current restrictive laws, it will be interesting to see whether there will be sufficient votes to override a veto by President Bush, Katherine Benesch with Duane Morris LLP in Princeton, N.J., told BNA. As research continues to advance, this issue will rise to the forefront as researchers hold out the promise of cures to many common diseases and conditions, and those cures depend in some way upon the use of stem cells.

Beyond Our Shores. International Health Law is in its embryonic stage, but should be on all health lawyers' radar screens, according to Elisabeth Belmont, corporate counsel with MaineHealth in Portland, Maine. Two recent developments illustrate the potential future significance of this area of the law, she said.

First, on Dec. 13, 2006, the United States formally accepted new international rules governing the respective roles of the World Health Organization and its member countries in dealing with public health emergencies that threaten other nations. More information on the International Health Regulations is available at http://www.who.int/csr/ihr/en. Also, on Oct. 24, 2006, Georgetown University announced the establishment of the Linda and Timothy O'Neill Institute for National and Global Health Law. The institute will include centers for global health, disease prevention and health outcomes, health regulation and governance, and health care financing. It will work with the World Health Organization to draft model public health laws; develop strategies for containing medical costs, improving health care quality, and disease surveillance initiatives; and explore using legal tools such as tax policy and zoning law reforms to reduce chronic disease.

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in incorporating and reviewing quality-related matters, including the accuracy of external quality-related reporting, as a compliance obligation given recent changes in the law and emerging FCA exposure for inaccurate quality data reporting,'' he added.

Peregrine also cited the ''rise of derivative litigation in the nonprofit arena and the role that 'mischief makers' on the board play—whether arising from a desire to reflect dissent or a good faith effort to challenge the general vision or specific actions of the board.''

He said Sarbanes-Oxley developments also should be watched ''as a variety of groups, including the Treasury Secretary and the U.S. Chamber of Commerce, seek to a find a new 'balance' in the evolution'' of corporate governance and responsibility laws. ''While such changes are likely to be characterized as a significant moderation of Sarbanes principles, they will have little practical effect on health care providers in the nonprofit sector, and actually carry the risk of sending a highly inaccurate and dangerous message that Sarbanes, in general, is being relaxed,'' he cautioned.

On the compensation side, Peregrine said, ''the significantly increased emphasis on disclosure will have the unavoidable effect of diminishing the value of delegating compensation decisions to the compensation committee, as much of the committee's work and recommendations will need to be reviewed again at the full board level to satisfy the interests of the IRS and especially of state charity officials that the full board is involved in compensation.''

Sullivan said that activity in this area appears to have slowed down slightly with the exception of state attorney general review of health care operations, charity care policies, and governing board oversight. ''With Generals Hatch and Spitzer now out of the limelight, we will have to wait and see if a new generation of activist attorneys general arises,'' he said.

Entin said many questions remain unanswered in the corporate governance arena, including ''what are best governance practices for non-profit boards and does one model suit all organizations?'' Although some of the ''frenzy'' surrounding the application of Sarbanes-Oxley principals may have abated, boards and their legal advisers are still adapting to an era of increased recognition of fiduciary duties, Entin said.

''Boards may be well advised to shift focus back to some of the traditional issues of governance of health care delivery organizations while still keeping their eyes on the SOx financial ball,'' he said. ''Expect more sophistication and demand for information regarding issues such as charity care, executive compensations, community benefit, quality, relationships with physicians and competition,'' he concluded.

Honorable Mention: Medical Staff. Wall said he believed medical staff issues will continue to command attention as conflicts arising from specialty hospitals to on call requirements of the Emergency Medical Treatment and Labor Act cause the rift between hospitals and medical staffs to grow larger.

Kadzielski said disruptive doctors are becoming the number one problem at health care entities everywhere. ''More and more medical staff leaders are summoning the courage to say to their colleagues after years of abusive behavior: 'enough is enough,' '' he said, adding that peer review increasingly will focus on professional conduct as well as professional competence.

Waxman agreed that the hospital-physician relationship is changing again, ''with physicians in leadership pods increasingly seeking to assert themselves in system development and being more creative in structuring their own roles, independent of, and often competitive with, the hospitals at which they have historically practiced.''

Hastings said 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 are acting more and more as competitors in the increasingly outpatient-based delivery environment and with their financial relationships governed by a slew of often conflicting laws.''

Sullivan predicted that, ''however challenging things may be between hospitals and their medical staff members now, I believe we will see accelerated business developments increasingly place physicians at competitive odds with their hospitals and another spurt in physician ownership and specialty hospitals.'' He also predicted a ''widening demand by physicians for payment for call coverage, which presents a host of contractual and regulatory issues and challenging questions of fair market value.''

Honorable Mention: Covering Uninsured. Finding ''new and innovative ways of covering the uninsured will continue to be a focus of politicians at the state, local and federal level, making it a likely issue in the 2008 presidential campaign,'' according to Wall.

Rovner agreed, saying the problem posed by the uninsured, and the success or failure of the ''Massachusetts experiment,'' could give rise to congressional and administration consensus and lead to some program innovations. ''How Massachusetts fares in implementing its 'universal' coverage experiment may substantially impact what Congress does in '08,'' he said.

Tuckman said 2007 is likely to see several states attempt to adopt universal coverage programs to address the un- and under-insured problem. ''The political winds and regulatory engines in many states are primed to adopt mandatory coverage programs for all employers or implement state run/sponsored single payor programs,'' he said.

''Despite the movement away from HMO to more choice-driven PPOs, the specter of universal coverage is politically enticing, a panacea for urban hospitals bearing a disproportionate share of the uninsured burden and increasingly palatable to the general public which views the existing system as personally expensive and complicated,'' he concluded.

Burde said he, too, believes the push for universal coverage will be a presidential campaign theme, but that it ''will be handled mostly at the state level'' and that ''the rhetoric will not be matched by the level of benefits actually offered.''

Honorable Mention: Professional Liability. Entin said the change in control of the House and Senate will more likely retard, if not completely derail, efforts to get reform at the federal level. ''Regardless, there have been reforms in many states as yet to be tested for constitutionality in court,'' he said.

''Whether these reforms pass constitutional muster will affect the willingness of commercial insurers to return to certain markets in the next year, although, even if they do not return with great vigor, insurance alterna-

tives are beginning to form,'' Entin said. While captives and risk retention groups are an answer for some, ''for others, there is some hope that new money will fund new liability insurance entities,'' he added.

''If more stability and predictability results from those reforms that have passed, there may be relief,'' he said. ''[R]ecent reports of 'medical tourism' and published interest by some employers and insurers in making care available overseas, will also require examination of a variety of liability, regulatory and insurance issues,'' he added.

Tuckman said there could be an increase in professional liability and other claims ''challenging the judgment exercised by innovative cutting edge clinicians and institutions.'' This trend, he said, stems from the fact that there have been numerous clinical innovations utilizing new drugs and devices.

''The pace of clinical innovation is much greater, however, than the regulatory oversight mechanisms and many clinicians have utilized drugs and devices beyond their 'approved use' for other apparently clinically sound purposes,'' he noted. ''A prime example is the multiple use of drug eluding stents. While clinical opinions certainly vary, recent evidence points to certain increased risks associated with nonapproved multiple uses,'' he said.

''As the case with investigational drugs and treatments, the focus will turn to whether patients were informed of the nonapproved use for these drugs and devices and whether the risks of such use were adequately disclosed,'' he concluded.

Kadzielski said that, because malpractice caps are taking effect in many states, he believed a new push for limits on those laws will be seen in the courts.

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