Lead Report

Outlook 2012

Regulatory Challenges, Uncertainty Make Health Care Reform Top Health Law Issue

Two years after they identified ''uncertainties surrounding pending health care reforms'' as the top health law issue for health lawyers, *BNA's Health Law Reporter* advisory board members again ranked health care reform as the number one issue facing providers in 2012, jumping ahead of fraud and abuse, which topped the list a year ago.

Board members asked to rank the Top 10 issues for 2012 chose health care reform as No. 1 because of wide-ranging challenges associated with implementation of the Patient Protection and Affordable Care Act and uncertainty over whether the U.S. Supreme Court will declare some or all of the statute unconstitutional.

Fraud and abuse ranked second this year; Medicare and Medicaid, third; antitrust, fourth; and quality, fifth. Rounding out the list were health information, health plan regulation, labor and employment, taxation, and corporate governance.

Most advisory board members said 2012 would be dominated by health care industry changes precipitated by health care reform, by ongoing compliance challenges posed by PPACA provisions already being implemented, and by the long shadow cast by a Supreme Court decision that cannot be predicted with certainty.

According to Thomas Wm. Mayo, of the SMU/Dedman School of Law, in Dallas, the Supreme Court's review of the PPACA decision ''isn't just the Case of the Term; it's the Case of the Decade.'' In the interim, however, as the country awaits that decision there is ''tremendous uncertainty in the industry at a time when the program challenges require quick and efficient action,'' Kirk Nahra, with Wiley Rein, in Washington, said.

Board members said 2012 will be marked by continued consolidation in the provider and payer arenas, new partnerships seeking to adjust to changing payment regimes, and increased and expanded enforcement efforts on numerous fronts, all against a backdrop of continued political and health care problem-solving gridlock.

Robert L. Roth, of Hooper, Lundy & Bookman, in Washington, pointed to a dysfunctional decisionmaking process underlying the Medicare and Medicaid programs, ''which results not only in the failure to address significant policy issues in a timely and deliberate manner but also in policies and positions that are, at times, contradictory.''

Dawn R. Crumel, with Children's National Medical Center, in Washington, said ''the number one issue facing many providers is building an integrated network to respond to the changing regulatory environment. Doing so is much more strategic than it was during the 90s boom given the increased financial and regulatory constraints.''

Health Law Reporter's Top 10 for 2012

Advisory board members ranked these the most important health law issues for 2012:

1. Uncertainty reigns as providers and payers attempt to implement a **health care reform** law that could be invalidated in whole or in part by the U.S. Supreme Court.

2. **Fraud and abuse** concerns proliferate with reform-related collaboration.

3. Changes to **Medicare** payment and challenges for **Medicaid** programs continue.

4. Threat of government **antitrust** enforcement exposes provider consolidation risks.

5. **Quality** continues to underpin third-party payment reform.

6. Final privacy and security rules keep **health information** hot.

7. The **health plan regulation** arena is dominated by PPACA health insurance reforms.

8. Unionization initiatives and a partisan NLRB create **labor and employment** challenges.

9. Implementation of PPACA's **taxation** requirements for exempt hospitals burdens IRS and providers alike.

10. **Corporate governance** concerns intensify with compliance and enforcement risks.

''Hospitals must examine trends for physician practice acquisitions, including the valuation process, and build affiliations with other health systems, which for many systems involves building a network internationally,'' Crumel added.

According to Douglas Ross, of Davis Wright Tremaine LLP, in Seattle, however, these are the very forces that will give rise to aggressive antitrust enforcement. ''This will continue in 2012, as will the belief of many in health care that the antitrust enforcers' insistence that small is beautiful is fundamentally at odds with the reality faced every day by providers: that they must grow and achieve scale if they want any realistic chance of surviving in a future when government payers crowd out commercial payers while simultaneously paying less than they ever have before,'' Ross said.

These same forces, that cause providers to move out of silos and into cooperative financial relationships, will also create fraud and abuse risk, board members noted.

''Fraud and abuse will remain the number one 'bet the company' issue for health care clients, whether drug and device manufacturers, hospitals, physicians, or other providers,'' Richard Raskin, of Sidley Austin LLP in Chicago, said.

All in all, board members agreed that 2012 will be a busy year for health care lawyers, and anything but boring, no matter how the Supreme Court rules and whichever way the political winds blow.

1. Health Care Reform

The myriad issues surrounding federal reform of health care will be the top topic of 2012, according to many *HLR* advisory board members. The chief focus, of course, will be on the U.S. Supreme Court's review of the challenged PPACA provisions.

The Supreme Court's review of the PPACA decision "isn't just the Case of the Term; it's the Case of the Decade."

THOMAS WM. MAYO

The high court, in November, granted three petitions that questioned the decision of the U.S. Court of Appeals for the Eleventh Circuit in *Florida v. HHS*, 648 F.3d 1235 (11th Cir. 2011). In 5.5 hours of oral arguments scheduled for March 26-28, the high court will consider:

- whether the Eleventh Circuit erred in holding that Congress did not have the authority to enact the individual mandate, a provision that will require virtually every U.S. citizen to obtain health insurance or pay a penalty;
- whether the individual mandate is severable from the remainder of the PPACA;
- whether PPACA's Medicaid expansion provision, which requires states to expand their Medicaid programs or lose federal funding, is unconstitutional as unduly coercive; and
- whether the tax anti-injunction act, 26 U.S.C. § 7421(a), which precludes courts from considering preenforcement challenges to the assessment and collection of taxes, divests the court of jurisdiction to hear the case.

HLR board members said they expect the second half of 2012 to be spent either on issues surrounding the implementation of PPACA—at least whatever is left of the statute after the Supreme Court rules—or developing new health care reform laws to replace PPACA if it is overturned as a whole.

'Nothing Else Even Close' ''Almost nothing else frankly is even close'' to the Supreme Court's ruling on the constitutionality of the health care reform law, according to Gerald M. Griffith, of Jones Day, in Chicago. ''This will be the top story of 2012, whether it's thumbs up or thumbs down, or they find a way to duck the question,'' he said.

''Both substantive issues (individual mandate and Medicaid expansion) are legal and political dynamite,'' Mayo, of SMU/Dedman, said. ''The Court could find itself a major player on the basis of almost any decision it renders.''

J. Mark Waxman, of Foley & Lardner, Boston, agreed. ''This is a no brainer,'' he said. ''Everyone is focused on what will happen.'' Raskin, of Sidley Austin, added that ''health care reform will remain a key legal and political issue.'' And Hooper Lundy's Roth challenged people to ''just try to get a seat in the Supreme Court gallery for that oral argument.''

Vicki Yates Brown, of Frost Brown Todd LLC, Louisville, Ky., told BNA the Supreme Court's decision ''will have ramifications for years to come'' and ''will be one of the most defining moments in health care in the next 3-5 years.'' She characterized it as ''one of the most impactful decisions the Court has made in years.''

Predictions. Davis Wright Tremaine's Ross predicted that ''the mandate will be struck down but it will be severed from most (but not all) of the remainder of PPACA.''

While ''it is certainly possible that the Court could rule that aspects of the law are unconstitutional, according to beltway insiders it is highly unlikely that the Court will wipe the law entirely off the books,'' Howard T. Wall III, of RegionalCare Hospital Partners Inc., in Brentwood, Tenn., said.

Katherine Benesch, of Benesch & Associates LLC, Princeton, N.J., noted that ''uncertainty created by the appeals accepted by the Supreme Court in cases involving the health care reform laws have stalled efforts at structural and financial changes to the system.''

''While some large hospital systems are working on developing ACOs to integrate providers in accord with the new federal regulations, many smaller institutions have adopted a 'wait and see' approach,'' she said. ''This approach appears to have taken over much of the health care system this year.''

Assuming the health care reform law survives in some form, its ongoing implementation will be the "biggest single challenge to the health care industry for 2012."

KIRK NAHRA

Current attempts to implement PPACA's mandates are being affected by the uncertainty over the Supreme Court's ruling, Jack A. Rovner, of The Health Law Consultancy, Chicago, said.

''Will the Supreme Court stop PPACA in its tracks, allow PPACA to barrel along unscathed, or lop off pieces but leave some or much moving along,'' he asked. ''If the last, will that intensify the confusion for states and industry (i.e., health insurers, providers, employers, etc.) faced with ever-shortening time frames to comply with PPACA mandates and adjust business practices to fit the post-PPACA health care world of health insurance exchanges, MLR rebates, ACOs and other integrated or coordinated care delivery systems?''

  HLR ISSN 1064-2137

Rovner nevertheless said he expects ''the politically and financially rocky road to PPACA implementation'' to ''continue unabated during 2012.''

Regardless of the outcome in the Supreme Court, ''the health care reform law will have a profound impact on the industry,'' Griffith said. ''If the law is upheld by the Supreme Court, it will be full steam ahead to implement as much as possible as soon as possible to beat back efforts at repeal.''

''If it is struck down but only in part, same scenario but with the added frenzy of payment reform to get more money into the health care system to cover the costs of the other aspects of the health care reform law,'' he said.

''On the other hand,'' he said, ''if the Supremes say the whole statutory scheme falls as unconstitutional, both parties will be under intense pressure to craft a compromise solution that addresses the needs of the uninsured and affects the financial health and quality performance of the health care system, including even tighter focus on alleged fraud, waste, and abuse if that's possible,'' Griffith said.

Industry Wildcard. Assuming the health care reform law survives in some form, its ongoing implementation will be the ''biggest single challenge to the health care industry for 2012,'' according to Nahra, of Wiley Rein. ''It will require coordinated and extensive efforts from all parts of a company, ranging from legal and compliance to finance and marketing and virtually everything in between.''

''At the same time,'' Nahra said, ''this legislation also is the biggest wildcard for the industry, and the Supreme Court's upcoming decision on the legislation may throw a complete monkey wrench into the overall reform effort.''

''Medicaid is the point where the health care reform rubber meets the affordability road.''

ROBERT L. ROTH

''If the reform legislation is permitted to proceed without Supreme Court intervention, we will see over the next few years a fundamental change to the overall health care system, mainly on the payment side,'' Nahra said. ''Payers face tremendous challenges in evaluating these new programs and transforming their business to meet these new competitive challenges and administrative requirements. In addition, we will see a tremendous blurring of the lines between payers and providers.''

''The administration has been faithfully churning out new regulations for these programs, but there is a real tension between developing appropriate regulations and not creating substantial disincentives to participate from the regulatory complexity,'' Nahra said. ''Companies will face the choice between spending time and money now—often large amounts with significant time pressures—on programs that may not exist or that may change significantly.''

Effects of Reform. ''If health care reform survives,'' Roth said, ''the biggest issue will be Medicaid.''

''Medicaid is the point where the health care reform rubber meets the affordability road,'' Roth said. ''States want to protect their budgets, the federal government wants to be accommodating, providers want reasonable payment, and recipients want decent care. It is doubtful that managed care will be the panacea that many states are hoping it will be.''

Even if PPACA does not survive, ''health care reform does not happen solely at the federal level,'' Foley & Lardner's Waxman noted. ''There is a great deal of innovation and change at the state level. . . . Within this framework, are a multitude of issues.''

2. Fraud and Abuse

The federal government in 2011 recovered billions of dollars in fraud settlements with health industry players. The lucrativeness of its increased enforcement initiative makes it unlikely that the government will treat providers any more gently in the coming year, according to *HLR* board members. Add in state anti-fraud activities, and providers must be more prepared than ever to defend against charges of misconduct, they said.

Health care fraud and abuse issues are ''always number one. Always,'' according to T.J. Sullivan, at Drinker Biddle & Reath, in Washington, one of several board members who voted for ranking fraud and abuse as the top issue.

Sanford V. Teplitzky, of Ober Kaler, Baltimore, told BNA he is confident ''there will be no shortage of work during 2012 for health care lawyers who focus on fraud and abuse issues.''

Specific issues to watch in 2012, according to Teplitzky, include the Centers for Medicare and Medicaid Services's Self-Referral Disclosure Protocol (SRDP). Although the SRDP has been in place since 2009, and was amended in 2011, to date, ''only one settlement has been made public'' although CMS reportedly has received over 130 submissions, Teplitzky said.

''This experience to date does not provide much comfort for the hundreds, if not thousands, of health care providers who may have identified noncompliant financial relationships with physicians,'' he said.

Teplitzky said his experience has been that ''the great majority of non-compliant relationships involve more operational or procedural noncompliance, e.g., missing signatures and expired agreements that otherwise would have satisfied the relevant exceptions. Understanding how CMS will address those issues will be critical in the decisionmaking process for providers considering the SRDP.''

Elisabeth Belmont, of MaineHealth, Portland, Me., also said the SRDP bears watching. Right now, she said, ''many questions relating to the process and how CMS might exercise its authority to compromise overpayment liabilities remain unanswered.''

Government Moneymaker. One reason fraud enforcement remains hot, board members said, is that it is an economic issue for the government. Nahra, of Wiley Rein, told BNA ''fraud has taken an increased place in the overall policy discussions, particularly the questions about how much health care costs and where savings can be found.'' Because federal budget calculations already have factored in large amounts of fraud savings, federal investigators and prosecutors will be feeling pressure to root out fraud and punish companies for misconduct, he said.

''The equilibrium of the normal enforcement process has been tilting towards the government for many years,'' Nahra said. He added that these economic/budgetary pressures, coupled with the wide range of aggressive tools held by the government and a commitment (as expressed by DOJ) to use these tools 'creatively and aggressively,' [could] create a tipping point in favor of the government and against potential defendants.''

RegionalCare's Wall noted that ''at a time when the two political parties can't agree on anything, the one thing they can agree on is maintaining and even increasing robust federal health care fraud enforcement activities.''

''When industry leaders and lawyers complain about excessive regulation and costly compliance programs, Congress has consistently resisted any serious effort to weaken fraud enforcement powers. Programs that are seen as reducing 'fraud, waste and abuse' in federal spending are unlikely to change even if the election produces a shift in power,'' Wall said.

Benesch, of Benesch & Associates, pointed out that ''with governmental power as leverage, fines against providers have become a major source of revenue at all levels of government,'' ensuring that ''health care fraud and abuse will continue to be the focus'' for federal enforcers.

Additionally, she said, states ''have been staffing offices of fraud prosecutors at record levels.'' This trend, Teplitzky said, ''may lead to increasing tension between the federal government and the states, and in fact, between one state and another. Here, the provider may feel that it is caught in a game of tug of rope, where unfortunately, the provider is the rope.''

Focus on Compliance, RCOD. To avoid government scrutiny, health care providers will want to strengthen their focus on compliance, board members said.

Hooper Lundy's Roth said the enforcement agencies are trying to ''shift the responsibility for compliance down to the provider level by requiring providers to have effective compliance plans,'' although they have not ''provided a clear articulation of any meaningful governmental benefit to providers'' who have done so.

Members of corporate boards of directors will increasingly look at compliance issues in 2012, as they may be the ones called in to account for any misconduct. In the past few years, the Department of Justice has begun prosecuting company executives under the responsible corporate officer doctrine (RCOD), and is unlikely to stop anytime soon, according to Belmont and Sidley Austin's Raskin.

Michael W. Peregrine, of McDermott Will & Emery, in Chicago, said he will be watching ''the direction DOJ and HHS OIG take in connection with RCOD enforcement as the Obama administration continues to focus on individual accountability for corporate criminal activity.''

Peregrine said ''particular areas of interest will be the resolution of the appeal of the Purdue Pharma executives' disbarment, whether any administrative or other guidance is provided on the 'impossibility defense' to RCOD violations, and on further applications of OIG's permissive exclusion authority, beyond the pharma and medical device sectors to the provider sector.''

Health Care Reform and Abuse. Other board members warned that increased fraud enforcement activity will follow from the implementation of health care reform measures.

''There is an obvious interest in the government in having these [health care reform] programs work,'' Nahra said. ''And, of course, the fraud and abuse risks (both the real risks to government programs and the perceived risks from participating companies) will impact in significant ways the success of these programs. Simply put, if companies are scared off by fraud and abuse risks, they will not participate, or will not participate as fully,'' he said.

Nahra said he ''will be watching carefully how the government (1) prosecutes and settles cases over the next year; (2) develops, implements and promotes regulations that protect the programs while still permitting and encouraging participation, and (3) whether these approaches will be maintained over time.''

One reform measure in particular could be in for a great deal of fraud and abuse oversight, board members said. SMU/Dedman's Mayo, for example, told BNA that attorneys should be prepared to represent accountable care organizations (ACOs), introduced as a means of saving costs by consolidating providers and spreading costs over various entities, when they come under federal scrutiny.

According to Waxman, of Foley & Lardner, the ''waivers of the regulatory issues for ACOs do not go far enough to support the broad spectrum risk sharing necessary outside the rigid ACO structure,'' leading to possible fraud and abuse challenges for providers.

''There will be no shortage of work during 2012 for health care lawyers who focus on fraud and abuse issues.''

SANFORD V. TEPLITZKY

Other reform-minded physician/provider alignments also will be subject to scrutiny. ''The health care industry is going to continue to struggle in the area of compliance due to significant industry disruptions which necessarily create new alignments,'' Brown, of Frost Brown Todd, said.

Brown told BNA she thinks ''the industry is going to struggle to more clearly identify the proper parameters to implement the measures foisted upon it in order to do business. Unfortunately, many of the compliance requirements were put into place for an entirely different health care delivery model. That model is now being reshaped and the antitrust and fraud and abuse regulatory requirements need to be revisited and revised to reflect this new delivery model.''

Health care attorneys also should watch out for fraud and abuse issues in connection with other reform-related developments, such as electronic health records (EHRs), according to W. Reece Hirsch, of Morgan, Lewis & Bockius LLP, in San Francisco. ''As hospitals move forward with the adoption of electronic health records and push those EHRs out to affiliated physicians, the Stark and anti-kickback statute safe harbors

  HLR ISSN 1064-2137

for EHR donations are going to be a focus of renewed attention,'' he said.

Data Mining, Coding Errors. Belmont also told BNA that practitioners should watch out for increased data mining efforts by the enforcement agencies. ''In 2012,'' she said, ''the reliance of both contractors and the government on data mining to help detect potential instances of fraud, waste, and abuse in federal health programs will continue to grow. Providers likely will be targeted based on utilization rates, prescribing practices and billing/coding profiles.''

''Moreover,'' Belmont said, ''publicly reported data regarding quality has the potential to be effectively mined by federal prosecutors for the purpose of bringing claims under the False Claims Act.'' She noted that ''the HHS Office of Inspector General has identified inconsistencies in quality data submitted by different individuals within the same organization.'' To avoid fraud claims based on such inconsistencies, ''health care organizations need to carefully review data that is publicly reported,'' she said.

Eric A. Tuckman, of the Advisory Health Management Group, Manhattan Beach, Calif., also warned health care attorneys to be on the lookout for coding and billing-related enforcement actions in the coming year.

''While proper coding has been a regulatory focus for the past few years, the coming year will bring new levels of focus/activity in the heightened scrutiny of sophisticated and integrated computer based coding and record keeping programs,'' Tuckman told BNA. ''These 'novel revenue cycle enhancement' practices will be closely examined, especially in restricted or closed clinical delivery systems.''

Jones Day's Griffith added that ''computer matching and using software programs to spot outliers that may be violations is not the stuff of science fiction any more. It's now science fact . . . and a way for the government to do more with less.''

Whistleblower Actions Remain Hot. Privately initiated litigation also will continue to be hot, board members said.

According to Teplitzky, there will be no ''let up in whistleblower actions under the Federal False Claims Act. In fact,'' he said, he believes ''government investigative and enforcement priorities will continue to be driven by private citizens who may be more focused on their financial recovery interests than on prudent health care policy.''

''The pipeline of health care and pharmaceutical qui tam remains well stocked, making it likely that the trend of multiple filings and newly unsealed complaints will continue through 2012 and beyond,'' Raskin said.

Also, since PPACA ''broadly expands liability under the False Claims Act and the anti-kickback statute,'' it ''opens the door to a wider range of whistleblower claims under its more functional analysis,'' according to Stephanie W. Kanwit, of Stephanie Kanwit LLC, Alexandria, Va.

3. Medicare and Medicaid

Medicare and Medicaid garnered a high position on board members' Top 10 lists because of their central role in funding health care providers and in driving health system change under health care reform. Compliance and enforcement headaches related to Medicare reimbursement, overpayments, and ACOs and the shared savings program were the greatest concerns to board members on the Medicare side.

On the Medicaid side, board members' concerns focused on state budgetary woes, the increased pressure on Medicaid programs caused by expansion mandated by health care reform, and the risks to Medicaid recipients if state reimbursement drops too low to attract the physicians needed to provide care to this expanded group. Litigation over state reimbursement also was cited as an important Medicaid issue to watch in 2012.

Medicare ranks high on the list because it is the focal point of the Obama health care reform plan that looks to shift the focus of the Medicare payment mechanism from fee-for-service to quality-based reimbursement and to utilize pay for performance, gainsharing, and other experimental quality-based payment mechanisms that are built into PPACA and related laws, Waxman, of Foley & Lardner, said.

''The question is whether these efforts will be too little too late,'' he said.

The way Medicare costs are managed . . . ''will define health care in the United States for the next generation.''

DOUGLAS A. HASTINGS

While payment reforms are critical, Waxman said, actual and disputed changes in the systems of payment are moving at a snail's pace. ''These do not seem to be significant enough to save the U.S. from some form of health care bankruptcy due to the inadequacy of the financing system to control or cover continually escalating costs,'' he added.

Douglas A. Hastings, of Epstein Becker Green PC, Washington, said the importance of Medicare cannot be discounted because Medicare costs will be the most challenging component of the federal budget in the years ahead. ''The way they are managed and the impact that management has on the health care system will define health care in the United States for the next generation,'' he said.

''While public sector and private sector payment system alignment is essential in the long run, Medicare as the single largest payer will drive the direction of health care payment and delivery,'' he added.

''The good news is that we are making progress directionally in understanding the challenges our health care system faces, the reasons for our cost and quality issues, and the broad framework for a higher performing payment and delivery system,'' he continued. ''As to implementation and success, however, there is significant unevenness around the country, and we have a long way to go.''

John D. Blum, of Loyola University Chicago Institute for Health Law, Chicago, said more Medicare cuts will have to be made beyond those already incorporated into PPACA and that it may be very challenging for safety net providers, in particular, to improve quality of

care processes and patient satisfaction to meet new value-based purchasing requirements.

Hooper Lundy's Roth cited the inability of Congress to fix the sustainable growth rate (SGR) and waffling on the role of effectiveness research.

With respect to the SGR, Roth noted that physicians are subjected every year to the threat of massive payment cuts, which typically are addressed at the eleventh hour and sometimes later. ''Physicians are one of the cornerstones of the Medicare program so it is hard to see how subjecting physicians to this annual Damoclean sword furthers any regulatory purpose,'' Roth said.

''The health care reform law also included a provision to fund research to determine which therapies are, in fact, effective. While it would seem to be a matter of common sense that the Medicare and Medicaid programs should not pay for ineffective therapies, Congress prohibited CMS from acting on the results of the effectiveness research,'' Roth said.

Roth also cited the agencies' efforts to cut off the ability of beneficiaries and providers to have access to the courts for review and redress of governmental decisions. ''This is squarely before the Supreme Court in the *Independent Living Center* case,'' which involves a challenge to the adequacy of reimbursement paid to providers under California's Medicaid program.

''Here again, the government is being particularly shortsighted because it should be encouraging, not squelching, input from the beneficiary and provider communities. Beneficiaries are the 'customers' of these programs and the providers are the 'caregivers,' and their views should be solicited, not avoided,'' he said.

Increased Litigation Over Medicaid. Tuckman, of the Advisory Health Management Group, said he expects to see, on a state-by-state basis, increased litigation—like that brought by Medi-Cal providers and recipients—challenging the appropriateness of dramatically decreased Medicaid reimbursement rates for providers and reduced benefits for beneficiaries.

Kanwit, of Stephanie Kanwit LLC, said the ''big news'' is ''the very positive use of Medicare to encourage change towards a more quality-driven system—by the mechanism of accountable care organizations and health care reform's shared savings and Pioneer ACO programs.''

ACOs ''are part of what I see as the new paradigm of collaboration among providers, and between health plans and providers as well,'' she said. ''From a Medicare perspective, however, the jury is still out on the effect the final ACO rules will have in terms of promoting collaboration that leads to higher quality and lower costs.''

MaineHealth's Belmont said the Medicare Shared Savings Program will cause physician and health care organization alignment issues to assume increasing importance in 2012.

''Physicians participating in ACOs also will need to address the multiple legal steps required in forming any new legal entity: (i) governance; (ii) tax structures and considerations; (iii) capital development; and (iv) contracts with third parties, such as vendors and claims and billing companies,'' she noted.

Roth also cited an enforcement approach by federal agencies that seeks to shift the responsibility for compliance down to the provider level by requiring providers to have effective compliance plans.

''This issue has become particularly important in light of the 60-day mandatory refund requirement enacted as part of health care reform because providers acting proactively under their compliance plans will likely identify and refund significantly more than providers who are less diligent about their compliance efforts,'' Roth said.

''Yet, the enforcement agencies have not provided any benefit, whether limiting the 'look-back' period or limiting the amount of the recovery for cooperative providers.''

Overpayment Headaches. Davis Wright Tremaine's Ross also cited Medicare ''overpayment headaches'' stemming from health care reform's overpayment disclosure obligation. PPACA providers must disclose and repay any overpayments received from federal programs within 60 days of the date the overpayments are ''identified'' or face potential False Clams Act liability, he noted.

Ober Kaler's Teplitzky, however, observed that ''there still is no definitive guidance as to when the 60-day time frame begins to run.'' He said he was hopeful that CMS will issue guidance on the issue soon.

''Knowing when an overpayment has been identified and how far back a provider may have an obligation to make repayment are important issues that will impact a provider's ultimate decisionmaking process with regard to such disclosures,'' he said.

''Medicaid will be hotter because of the ramp up to huge coverage increases under PPACA . . . .''

T.J. SULLIVAN

Fredric J. Entin, with Polsinelli Shughart PC, in Chicago, said hospitals also will continue to face significant challenges dealing with recovery audit contractors in the Medicare program and, starting in 2012, will face the added challenge with respect to Medicaid payments.

''The key for providers is to manage the audit process—by learning how to respond effectively to requests for records and to engage in critical analysis to get and stay ahead of the game—and document everything to make sure an appropriate administrative record is developed,'' he said.

With respect to Medicaid, Waxman said state governments simply cannot cope with the cost of a 50-50 Medicaid split, unless major reforms to the model for health care financing are implemented. ''These are not on the horizon, Congress has not appeared to be willing to step up to the plate to make the required change away from fee-for-service medicine, and while demonstration projects are proposed and being considered, health care inflation is fast outpacing the rate of change in the payment mechanisms,'' Waxman said.

Blum ranked Medicaid at the top of his list, citing state budget crises, unemployment, and health care reform as forces that are placing ongoing pressure on states to reform their Medicaid programs. ''Most have moved in the direction of managed care reforms but it

  HLR ISSN 1064-2137

isn't clear that recent changes will be adequate to meet demands of expanding low income adults and children,'' Blum said.

Drinker Biddle's Sullivan agreed. ''Medicaid will be hotter because of the ramp up to huge coverage increases under PPACA, contrasted with state budget pressures, leading to potential cuts such as those recently proposed by Florida's governor.''

Blum also cited pressures of long term care that have not been adequately addressed in reform initiatives. ''The demise of the Community Living Assistance Services and Support Act places even greater pressure on Medicaid as the primary public payer in this area.''

Rovner, of The Health Law Consultancy, agreed, saying ''cash-strapped states will continue to struggle to deal with PPACA's Medicaid expansion, a struggle that will be made more difficult as state Medicaid agencies try to figure out how to manage the cusp between Medicaid eligibility and exchange subsidy eligibility.''

4. Antitrust

The pressure to consolidate provider operations that is coming from all sides, and affecting all players, kept antitrust near the top of this year's Top 10 list for many board members. Like other areas, antitrust compliance and enforcement challenges are a key concern for payers and providers both because of and apart from health care reform, they said.

Consolidation is being pushed at all levels by changes in reimbursement, by the country's economic problems, and by health care reform initiatives such as the Medicare Shared Savings Program, and is creating a formidable compliance and active enforcement climate, board members said. This climate exposes a palpable tension between the need to spur innovative collaboration and the need to preserve competition, they added.

According to Tuckman, of the Advisory Health Management Group, the level of merger and acquisition activity over the past year ''has increased exponentially'' both at the institutional level and with respect to physician delivery organizations. ''Many strategic discussions that were initiated this year will result in transactions next year,'' he said.

''Heightened levels of regulatory enforcement activity will continue and will result in proceedings that focus and highlight the inherent disconnect between traditional antitrust concepts and political and market forces that are driving greater provider alignment, integration, and collaborations,'' he said.

Waxman, of Foley & Lardner, agreed, noting the ''continuing stream of mergers and acquisitions up and down the health care delivery system,'' with plans acquiring providers, providers looking at plans, and hospitals acquiring other hospitals. ''The market is changing. Where it will end up is just not known.''

Continued M&A Boom. RegionalCare's Wall predicted a continued boom in health care M&A and hospital/physician alignment activity. ''In-market competitors will merge or be acquired, standalone hospitals and systems will affiliate or be acquired by regional or national players, and hospitals will continue buying practices and employing physicians,'' Wall said.

Michael F. Schaff, of Wilentz, Goldman & Spitzer, in Woodbridge, N.J., said physician/hospital alignment will continue despite what many physicians see as significant challenges and risks.

''Physicians feel like they need to do something but are afraid of change, concerned about the loss of autonomy that being employed by a hospital entails, and worried about what will happen if they decide to return to private practice,'' Schaff said. ''Many, however, are finding the use a physician enterprise model—under which they essentially lease their practices to a hospital and retain a measure of control—can be an effective way to address these concerns and manage risks,'' he added.

Davis Wright Tremaine's Ross said the employment of physicians by hospitals and hospital consolidation activities that accelerated in 2011 will continue in 2012. Physicians will continue to see hospital affiliation as a path to increasing reimbursement and achieving a better work-life balance while hospitals will merge and grow in order to be better positioned to take risk and achieve efficiencies, he said.

''There is no end in sight: most hospitals cannot stand alone if they want to stand at all. The extraordinary regulatory burden, costs, and now business risks imposed on hospitals can only be absorbed when hospitals are part of a system,'' Ross said.

''The extraordinary regulatory burden, costs, and now business risks imposed on hospitals can only be absorbed when hospitals are part of a system.''

DOUGLAS ROSS

He said he anticipates some ''interesting twists in consolidation in 2012,'' predicting an increasing number of health system and hospital affiliations between Catholic and non-Catholic institutions and an increasing number of affiliations between academic medical centers and community hospitals geared to ensuring one thing: ''survival.''

He also said he expects more acquisitions of community oriented nonprofit hospitals by for-profit companies.

Epstein Becker's Hastings cited the Final Policy Statement on ACOs as an important acknowledgment by DOJ and FTC that CMS's requirements for ACOs align with their historical thinking about clinical integration.

New Forms of Contracting. ''Many providers out in the field struggle with understanding the complexities of antitrust law as it applies to their activities. It is useful for the agencies to reinforce to providers coming together to collaborate in ACOs that if they drive real change toward better outcomes and cost efficiency, they will not be subject to the potential per se treatment,'' Hastings said.

''In my view, there is the potential for new forms of contracting—rather than mergers—among providers, including in some cases high market share providers, working with payers, to accomplish accountable care

goals through bundled and global payments to create antitrust-acceptable pathways,'' he continued.

Kanwit, of Stephanie Kanwit LLC, said concerns remain about the rush to consolidate, the reduced provider competition that would result, and the possible impact on health care markets. The final antitrust guidance makes it easier for ACOs to form but will make it significantly more difficult for the agencies to police ACOs that lead to undue market power after the fact.

With respect to enforcement, Toby G. Singer, with Jones Day, Washington, said 2012 should be ''a very active time for antitrust enforcement because, for the first time in a while, both U.S. antitrust agencies are aggressively bringing cases.''

She noted that the FTC brought three hospital merger cases in 2011 and that DOJ is litigating its case against Blue Cross Blue Shield of Michigan over its use of MFN clauses in contracts with Michigan hospitals. DOJ also settled cases with a large health plan—Blue Cross Blue Shield of Montana—and a large health system—United Regional Health System—for allegedly engaging in anticompetitive conduct.

''In addition to these efforts, ACOs, physician mergers, and follow-on private cases—those brought after government actions—are likely to be hot areas,'' she said.

Competitive Impact of ACOs. Sidley Austin's Raskin agreed, saying he expects to see more hospital merger challenges, and more debate about the competitive impact of ACOs.

''In the pharmaceutical sector, expect continued close scrutiny of patent settlements, authorized generics, and citizen petition filings from FTC and the plaintiffs' bar. Private antitrust claims involving alleged generic exclusion are also likely to increase,'' Raskin said.

Rovner, of The Health Law Consultancy, said ''there is lots of antitrust fuel in the health care market in 2012'' and predicted there could be challenges to ACOs as creating market power by consolidating or coordinating through joint ventures, new challenges to most favored nation/exclusivity clauses used by dominant health insurers in their provider contracting, and actions brought over payer-provider ''sweetheart'' deals in which dominant provider systems and dominant payers craft contracts to protect their respective turfs by agreeing to disadvantage their respective competitors.

Rovner also said he expects there could be a spike in private antitrust actions in 2012. ''Payers, employers, or even individual patients could bring actions against consolidated provider groups claiming they are exercising illegally-gained market power to inflate commercial market pricing,'' he said.

''Private parties also could challenge allegedly anticompetitive health insurer-provider contracting practices or health insurer consolidation, a trend that is likely to continue as capital and resource demands increase for effective entry into new markets like health insurance exchanges, Medicare Advantage, Medicare Part D, and Medicaid managed care,'' he added.

Tuckman said he expects a ''significant portion'' of increased regulatory activity to involve new challenges to hospital ownership of components of the physician delivery system that is viewed by regulators as anticompetitive.

Novel Attempts to Justify Mergers. ''Contrary to the strategies in the past, where improved operating efficiencies and resultant cost savings was one of the principle defense strategies utilized, we are likely to see, especially in urban markets, legal strategies where M&A activities are justified on the basis of responding to preserving patient access and compliance with new payer mandated reimbursement practices,'' Tuckman predicted.

''We will also likely to see numerous novel attempts by hospitals and health systems to justify mergers that would traditionally exceed acceptable market share levels on the basis of long-term poor operating performance—performance that does not rise to the traditional levels supporting a 'failing firm' defense,'' he added.

Ross said that there is no question that the federal antitrust agencies are aggressively reviewing health care mergers and acquisitions. ''The agency is zealously reviewing hospital mergers in addition to pending cases and even acquisitions of small physician practices can draw scrutiny and opposition,'' he said.

''The aggressiveness of the FTC will continue to be seen in its won/loss record. Although the agency lost some important cases in 2011, including its challenge to the LabCorp merger in a federal court in California, and while it continues to get nowhere in the courts on its challenges to so-called 'pay for delay' arrangements, don't look for change in the FTC's approach in 2012,'' Ross said.

5. Health Care Quality

Health care law attorneys may find themselves focusing more on quality issues in 2012 than ever before, *HLR* board members said. Many health care reform initiatives use quality as a benchmark and, thus, providers that wish to maximize reimbursements and minimize liabilities will be looking for ways to improve quality over the next several years.

Quality performance ''will become the basis for excluding underperforming providers from both government and private networks entirely.''

HOWARD T. WALL

Health care quality also will figure in legal issues beyond reimbursements, as providers look for ways to share information that can lead to quality improvements without incurring liability for disclosing private information or losing privileges that protect such information from public dissemination.

Defining Quality. Quality of care, according to an Institutes of Medicine definition, is ''care that is safe, effective, efficient, patient-centered, timely and equitable,'' Epstein Becker's Hastings said. ''That definition became the basis for the payment and delivery of reform components of PPACA and the core concepts in the Medicare Shared Savings Program Final Rule.''

Now, a new chapter is beginning in which providers will see the ''potential widespread effective implemen-

  HLR ISSN 1064-2137

tation of those ideas (or not) and a consequent positive and measurable impact on outcomes, patient satisfaction, and cost efficiency (or not),'' Hastings said.

RegionalCare's Wall added that, ''with the implementation of the hospital value-based purchasing program, the development of ACO quality standards, the rollout of physicians core measures reporting and the proliferation of private pay-for-performance programs, the spotlight will continue to shine on the ever complex quality performance measures.''

''Quality performance will no longer be just the basis for lower reimbursement; it will become the basis for excluding underperforming providers from both government and private networks entirely,'' he said.

According to Benesch, of Benesch & Associates, ''quality of care is more important, as outcome measures are becoming the basis for reimbursement for services rendered.'' Other board members agreed that using quality of care measures to determine reimbursement will be a challenging issue in 2012.

''The whole issue of how to achieve better quality health care at lower cost is the central conundrum that PPACA addresses,'' Kanwit, of Stephanie Kanwit LLC, said. ''The act addresses quality at many junctures, and attempts to lay the groundwork for the 'big picture' initiatives that help us achieve quality.''

Belmont, of MaineHealth, agreed, but said the task of ''translating these quality initiatives into actual commitments such as contracts and policies for hospitals, physicians, managed care organizations, accrediting organizations, and others'' will be even more challenging. The task ''will require an understanding of: (i) actual quality metrics—what is being measured and how, and reporting it; and (ii) the differing perspectives of payers, hospitals and physicians,'' she said.

Beyond Reimbursement. But health care quality issues go beyond reimbursement and meeting regulatory goals, board members said.

For example, Mark A. Kadzielski, of Fulbright & Jaworski LLP, Los Angeles, said, California has penalized ''its hospitals for serious adverse events to the tune of almost $8 million in the last four years.'' This ''may provide a model for how budget strapped state health departments can raise operating revenues.''

Belmont cautioned that quality information required to be reported could ''be used in professional liability claims against physicians for failing to adhere to the published quality mandates as well as corporate negligence or negligent credentialing lawsuits against hospitals for failing to adequately protect patients from harmful practices occurring within their walls.''

Also, she said, under the Health Care Quality Improvement Act, ''hospitals face significant liability exposure from physicians who bring legal challenges to practice restrictions or loss of privileges as the result of hospital enforcement of quality standards if the standards in HCQIA are not met.''

Belmont said that, ''even if the adverse privileging action is upheld after HCQIA process, hospitals still may face a lawsuit by the disciplined physician alleging antitrust violations, civil rights violations, breach of contract, defamation, and tortious interference with present and future economic relations.''

Mayo, of SMU/Dedman, summed it up, saying this is ''another of those cross-cutting issues that involve all providers, payers (public and private), regulators (especially the Health and Human Services Department's Office of Inspector General and the Internal Revenue Services with respect to gainsharing), ACOs, antitrust enforcement (quality goals and procedures as indicia of integration), etc.''

6. Health Information

How providers gather, use, and protect health information will grow into an important issue in 2012, as new regulations interpreting the Health Insurance Portability and Accountability Act and PPACA mandates come online.

Health care attorneys will have to address HIPAA developments, such as the extension of the privacy and security rules to business associates, which potentially creates new duties and liabilities for all. Additionally, several PPACA provisions require providers to adopt new means of storing and sharing private health information.

The ever-increasing use of social media by providers, patients, and others also will challenge attorneys in 2012.

'Always Hot.' Issues surrounding health information will be prominent in 2012, several *HLR* board members said. As SMU/Dedman's Mayo put it: ''Health information—always hot, likely to get hotter.''

''This is the architectural element upon which ACOs (and other forms of provider integration) will increasingly be built,'' Mayo said. ''It provides the tools for coordination of care among providers, for evidence-based medicine, and for improved quality of care.''

Brown, of Frost Brown Todd, agreed that ''health care information must rank as one of the top issues of 2012, as the industry continues to collect and share data . . . in order to meet reimbursement requirements'' and attain the clinical and financial integration required for new health care delivery models. ''This will create greater privacy and security compliance issues for the industry,'' Brown said.

Kanwit, of Stephanie Kanwit LLC, called PPACA a ''game-changer'' in the move to ''modernize the nation's health care system,'' as it requires adoption of health information technology.

PPACA is a ''game-changer'' in the move to ''modernize the nation's health care system.''

STEPHANIE KANWIT

''The big question,'' she said, is whether ''health care reform is likely to fulfill its promise to use policy and market forces to drive IT adoption.'' Kanwit said that ''as we head towards what some have called the 'digitization of health care,' we still have to reconcile the dichotomy between the micro and macro: data on a particular provider's individual encounters with patients, where there is usually limited concern about cost, versus an emphasis on the cost of care across the continuum, taking into account the needs of a whole population of patients.''

New Privacy, Security Regulations. Several board members also commented that the expected release of the final HIPAA/HITECH privacy and security rules—''after an almost three-year delay,'' Wiley Rein's Nahra said—will keep health lawyers busy in 2012.

''This development,'' Nahra said, ''will be coupled with increased enforcement,'' although ''it remains to be seen whether the government will issue realistic and reasonable regulations (as were largely set forth in the proposed HITECH rules), or will veer towards enormously burdensome rules with little privacy benefit (as they did with the proposed rule on the accounting provisions of HIPAA).''

The final rules are expected to include provisions governing business associates. Morgan Lewis's Hirsch told BNA that these entities ''will finally be faced with a concrete compliance deadline for implementation of HIPAA Security Rule standards and there will be a flurry of activity to develop or refine security compliance programs.''

The ''expansion of the business associate requirements,'' however, ''will create more confusion, and more opportunity for claims against providers and vendors for privacy breaches'' in 2012, Fulbright & Jaworski's Kadzielski said.

''Litigation between providers and vendors, who represent that they will protect private health information but do not have effective systems to do so, will also increase—and 'HIPAA Fingerpointing' will grow as more claims are made by everyone involved in handling patient data,'' Kadzielski said. ''Carefully drafted business associate agreements need to be utilized, especially with those entities that do not have proper insurance coverage for such data breaches.''

Federal Enforcement to Increase. Federal enforcement of the HIPAA privacy and security rules could take a more prominent role in 2012, Rovner, of The Health Law Consultancy, said. The public reporting of several large health industry data breaches has confirmed that the industry has not taken health information privacy and security ''seriously,'' Rovner said.

This could change, according to Hirsch, as the Health and Human Services Department's Office for Civil Rights, which administers HIPAA, ''is scheduled to complete 150 HIPAA audits'' by December 2012. He said that it will be very interesting to learn, ''as those audits proceed, how hard-nosed OCR is going to be and what compliance areas they choose to emphasize.''

Rovner agreed that the health care industry in 2012 ''may actually see serious enforcement of data privacy and security obligations.''

Private Litigation Likely. Even if government enforcement lags, Jones Day's Singer said, the risk of private litigation over data breaches will increase, and likely will expand to encompass software vendors. Health care providers and vendors of software related to electronic health records (EHRs) ''will continue to butt heads over issues like limitation of liability and indemnification,'' Hirsch added.

MaineHealth's Belmont noted that ''it is unknown how the law may develop over time to allocate liability fairly among individual practitioners, provider organizations that select and implement clinical information systems, and EHR system developers and vendors. Liability that arises primarily because of poorly designed EHR systems arguably should rest with those in control of system architecture and implementation, not end users.''

Belmont also cautioned that ''EHRs also can create new forms of potential risk and liability for health care providers in the areas of documentation of clinical findings, recording of test and imaging results, computerized physician order entry, and clinical decision support.''

''As with any new technology, the risk of error increases during the implementation phase, as health care practitioners and institutions transition from a familiar system to a new one,'' she said. ''Individual mistakes in using EHRs or system-wide EHR failures that create problems in patient care processes can adversely affect clinical care resulting in patient injuries and subsequent malpractice claims.''

There is no doubt EHRs ''will enhance the delivery and quality of patient care in short order,'' according to Wilentz's Schaff. And ''facilities and physicians will continue to be challenged to move their records into compliant EHR systems in 2012,'' Loyola University's Blum said.

Technology Increases Risk. Belmont advised that health care entities should be especially wary ''of increased risks arising from the growth of wireless networks, smart devices and other portable media, cloud computing, and more complex and multi-party data sharing arrangements among providers as well as the threat of stiffer breach enforcement actions.''

Providers' use of social media channels ''to connect with patients and improve health outcomes . . . presents an increased risk of the unauthorized disclosure of protected health information,'' she added. Belmont said providers should ''implement and enforce detailed social networking policies and integrate those policies with their human resources disciplinary policies'' in order to meet their continuing obligation to protect private health information.

''2012 is the year that will determine the winners and losers in the race to capture HITECH dollars.''

HOWARD T. WALL

Potential liability issues, she said, include inadvertent disclosures, ''re-identification'' of de-identified data, and online medical advice. ''It is important for clinicians to understand when to take the conversation off line so that they are not practicing medicine online in a public forum, possibly with an individual with whom there is no preexisting patient relationship,'' Belmont said.

Transition to EHRs. RegionalCare's Wall said ''2012 is the year that will determine the winners and losers in the race to capture HITECH dollars'' intended to speed the conversion to EHRs. ''Beyond simply 'checking off the box' to get the meaningful use dollars, the real winners will be the providers and health systems that actually use IT to improve outcomes, increase uniformity of care, reduce redundancy and waste, and improve the health of the population,'' he said.

The transition to interoperable EHRs while protecting data privacy and security, however, is likely to con-

  HLR ISSN 1064-2137

tinue to be not fast enough, according to Rovner. Additionally, he said, ''the cost in dollars, time, resources and complexity—especially in these economically depressed times and with all of the other demands on health care by PPACA and so much more—makes it likely that reaching the electronic 'tipping point' in the health care system will remain years away.''

The same could be true of health information exchanges, although, according to Nahra, ''2012 could be a make or break year'' for this development.

''To date, enormous sums of money and tremendous time expenditures have been spent with very little to show for it,'' he said. ''Moreover, while health information exchanges present the real possibility of both improved care and decreased costs, the developments to date point towards a situation where these networks are being built with little chance of success. In particular, the front end development costs are far exceeding expectations, there is little in the way of a business model for these networks, and the privacy restrictions that are being imposed on virtually all of these networks seem to guarantee that the information in the networks will be fragmentary and unreliable, thereby defeating much of the core purpose.''

7. Health Plan Regulation

Health insurers, states, and employers all will face significant challenges because of health care reform, making health plan regulation a key legal topic for health care attorneys in 2012, *HLR* board members said.

While they recognized that the landscape could change depending on how the Supreme Court resolves the health care reform law challenges, their comments focused primarily on health insurance exchanges, medical loss ratios (MLR), and cost containment pressures that are causing a ''proliferation of new payment models.''

Rovner, of The Health Law Consultancy, said pressure on states to develop the legal, financial and technical infrastructure to establish health insurance exchanges in each state should intensify during 2012. ''Those states that want to establish their own exchanges will scramble to be able to launch in time to be operational by October 2013, when open enrollment for health insurance through exchanges is supposed to begin,'' he noted.

''Republican-controlled state governments, resisting (to put it gently) PPACA implementation, will grapple with whether they'd rather tolerate a federally operated exchange in their state or take the federal money to establish an exchange that satisfies the very PPACA they oppose,'' Rovner continued.

''Meanwhile, health insurers will have to prepare products, marketing strategies, and more—if they hope to succeed as exchange participants starting with the October 2013 open enrollment—and state Medicaid agencies will have to figure out how to interact with exchanges to manage 'transitional' enrollment of individuals who may move across the line between Medicaid eligibility and exchange subsidy eligibility,'' he added.

Cost Considerations. Rovner also noted that, just as the case with providers, cost considerations will both drive and be affected by developments that are expected in this arena this year.

''Health insurance exchange operations, which are likely to be funded by health insurer assessment; 'unreasonable' rate increase reviews; medical loss ratio (MLR) rebate administration activities; uniform summary of benefits and coverage distributions; guaranteed issue, preexisting condition exclusions; and lifetime and annual limit prohibitions all entail costs that will have to be accounted for and dealt with,'' he said.

Foley & Lardner's Waxman said he expects an increase in state regulation of health plans and provider contracting. ''In the effort to control costs, there is a movement toward premium review, rate review, and a greater degree of oversight of plan-provider relationships,'' he said.

Wiley Rein's Nahra noted that ''health plans obviously were a major target of health care reform that, unlike many health care providers, seem to generate little sympathy from Congress or regulators in dealing with their current business challenges.''

The success of health care reform as a whole ''could hinge on whether the new developments allow for reasonable and reasonably priced health insurance products that still permit an appropriate business marketplace for health plans,'' Nahra said.

''This may translate quickly into whether insurance opportunities outside of health plans and the employer based health insurance system will develop. This is very much an open issue,'' he said.

''The challenge for the government is how to design and protect these programs while still permitting reasonable insurer participation. There is little indication to date, however, that the government is acting in a way that is designed to reduce or minimize the regulatory burdens on health plans from these new programs,'' Nahra said.

''Rather, health plans face enormous challenges in the years ahead in dealing with all of these new programs, and the government's focus on regulatory detail is making this challenge even more complicated.''

''Health plans face enormous challenges in the years ahead . . . .''

KIRK NAHRA

Ross, of Davis Wright Tremaine, said he also was expecting an increase in the level of innovation involving providers and commercial payers, including employer sponsored health plans. ''The payers appear to be more willing to experiment with new delivery models and bundled payments and these experiments can be scaled and designed by the payers and providers on an individualized basis, unlike government programs,'' Ross noted.

''Commercial payers also are starting to acquire providers, particularly primary physicians,'' Ross said, adding, ''if this trend continues, payers could be in a position to direct the flow of patients within more narrowly defined provider panels.''

New Payment Methods. Kanwit, of Stephanie Kanwit LLC, cited a ''huge proliferation of new payment models'' as ''good news'' for health plans and consumers stemming from health care reform. She cautioned, however, that ''there are no 'best practices' for these new

payment models, at least not yet, because they are highly varied and changing quickly.''

Kanwit also cited the MLR rule as posing significant challenges for insurers.

She said there is a conflict in the PPACA definition of ''quality improvement,'' which is very broad, and the final MLR rule issued in December. The statute mandates the percent of health insurance premiums that must be spent on reimbursement for clinical services and quality improvement activities.

''The act defines the terms as applying not only to making the delivery of health care more effective and of higher quality, but also more efficient, thereby lowering total cost of care,'' she noted.

''Unfortunately, the final rule contained a narrow definition of 'quality improvement activities' that would exclude health plans' expenditures on anti-fraud activities—such as ferreting out unlicensed practice, falsification of medical records, and even enrollee safety issues like medical identity theft and substance abuse,'' she said.

''Further, there is some concern that the MLR rules may prove to be anticompetitive or at least work against consumer 'choice,' as smaller or state-based insurers find themselves unable to fund new product development,'' Kanwit continued.

''Some insurers have already announced the intent to leave specific state markets, citing higher costs of operating in various state markets under heterogeneous rules, which have been exacerbated because of granting of 'waivers' by HHS,'' she added.

Howard A. Burde, of Howard Burde Health Law LLC, Wayne, Pa., said the MLR rules, at a time when the country is in a recession and health care costs are continuing to rise, could tip the balance and convince providers to decide that risk bearing makes more sense than ever. ''MLR restrictions on payers and the availability of data to actually manage care, is driving provider risk bearing to a degree not seen since the late 1980s and early 1990s,'' Burde said.

8. Labor and Employment

Health care is a service industry, and close attention must be paid to the rules governing the people who provide those services, health law attorneys say. Thus, attorneys practicing in the health care field must familiarize themselves with everything from collective bargaining agreements to social media policies. Developments likely to occur in 2012 will present a challenge for those attorneys, *HLR* board members said.

Proposed NLRB changes in union election procedures will ''significantly tilt the playing field in favor of the unions.''

JOHN E. LYNCHESKI

According to John E. Lyncheski, of Cohen & Grigsby PC, Bonita Springs, Fla., the ''most significant development in the Labor & Employment arena'' for 2012 will be the changes in union election procedures being pushed by the National Labor Relations Board.

The changes, which likely will be finalized within the next few months, ''turn union election procedures on their head and significantly tilt the playing field in favor of the unions,'' Lyncheski said.

The ''most significant'' change, Lyncheski said, ''is a major reduction in the amount of time between a union's filing of a Petition for Representation at the NLRB and the timing of the election.'' NLRB elections typically take place within 42 to 45 days of the filing of the petition. Once the changes go into effect, an election could occur within as few as 10 to 15 days, he said.

''This will severely limit an employer's ability to communicate with the employees in the voting unit so that they have all sides of the relevant issues and the applicable considerations. The changes would also limit the issues that an employer can litigate and have resolved before the election,'' Lyncheski said.

Wall, of RegionalCare, predicted that health care ''will continue to be fertile ground for union organizing activity.''

Employment-Related Issues. On the employment side, Lyncheski said, ''perhaps the most significant issue will be the play out of the U.S. Supreme Court's decision in *Wal-Mart Stores Inc. v. Dukes*, 131 S. Ct. 2541 (2011).'' This decision addressed employee class certification requirements, he said and ''impacts virtually every class action case pending and to be filed in the federal courts.''

Also worth noting is the continued movement toward employed physicians. There are several factors driving this movement, including ''reductions in physician reimbursement and social factors, such as a desire by younger doctors to be employed and avoid the risks—and hassles—of private practice,'' according to Davis Wright Tremaine's Ross.

To help ensure success of ACOs and other provider alignments, health systems likely will ''expand the use of physician extenders and telemedicine as the task of providing primary care, particularly in isolated locations, will go from challenging to almost impossible,'' Wall said.

''The looming doctor shortage combined with an aging physician population, the surge of baby boomers who will retire over the next two decades and the newly insured, will stretch the current system beyond the limits,'' he added.

Employee Benefits. Employee benefits issues also will challenge health care entities in 2012, according to MaineHealth's Belmont. In particular, health care providers will face issues growing out of employee wellness programs—both their own and those of their clients—as the rising costs of employee health care prompts employers to find ways to reduce their expenses.

Wellness programs can affect costs through incentives and disincentives, Belmont said, but they may be vulnerable to attack under state and federal discrimination and privacy laws.

With the growth of technologies that allow employees to work remotely ''24/7, 365 days a year,'' health care employers also must be aware of the risk that employees will work ''off the clock,'' she said. When this happens, Belmont said, ''employers may find themselves being subject to the 'continuous workday' doctrine, which makes employees' typically non-

  HLR ISSN 1064-2137

compensable commuting time part of the continuous workday and, therefore, compensable.''

Belmont advised that health care employers should ''carefully review their remote e-mail and remote access infrastructure and revise remote work policies to minimize the risk of off-the-clock work by non-exempt employees.''

Social Media Concerns. Belmont also noted that the ''ever-growing popularity of social media presents myriad issues for health care employers, and new issues will continue to emerge as technology continues to develop.'' She said it ''is critically important for health care organizations to review and modify their human resource policies, employment agreements and practices to address employee use of social media, including the right of the employer to monitor and search employee use of social media on employer-owned equipment.''

According to Belmont, some of the workplace issues likely to arise from employee social media use include: (1) workplace harassment; (2) discrimination claims based on pre-employment internet screening; (3) employee postings of confidential employer information, patient private health information, or defamatory statements; and (4) identity theft.

9. Taxation

Taxation remains a Top 10 issue for 2012, according to *HLR* board members, because of two main compliance and enforcement challenges: still evolving rules for tax-exempt hospitals under Internal Revenue Code § 501(r)—added by PPACA—and state and local taxation of these hospitals.

While the tax treatment of ACOs and tax implications of PPACA's insurance provisions for insurance companies and employers add an additional layer to these challenges, several board members predicted 2012 will see increased attention by state attorneys general to exempt health care organization activities and transactions.

According to Drinker Biddle's Sullivan, 2012 will be a busy and challenging year for the IRS and health care tax attorneys alike.

'Herculean Tasks.' ''IRS has been given Herculean tasks in implementing PPACA, largely without additional resources. While the agency has committed some of its smartest people to that effort, it unfortunately means that more routine health care tax matters have been shifted to the back burner,'' he said.

''Despite the fact that IRS provided some quick guidance on ACOs, the time frames for routine IRS rulings and technical advice are growing longer and new hospital Form 1023s are being held in the national office pending the release of Section 501(r) guidance,'' he added.

''As practitioners, we may be called upon more often to facilitate transactions based on opinions of counsel rather than taking the time to seek advance IRS approval. In contrast, IRS has not slowed its examination and enforcement activities—that involve different staff—so hospitals should not be tempted toward complacence,'' Sullivan continued.

''Congressional pressure for robust IRS enforcement of charitable organization rules continues, even if budgets have not been greatly increased. Each year, as experience is gained under Section 4958 of the Code, agents become more aggressive in examining executive compensation and other transactions with disqualified persons,'' he added. ''This year will be no different.''

Jones Day's Griffith, too, said his focus is on issues related to 501(r) implementation.

''We have interim guidance on the community health needs assessment requirements, but it is likely the IRS in 2012 will issue guidance on other aspects of 501(r), including billing and collection limits, financial assistance policies, the limitation on charges, how the exemption standards will be applied to unincorporated hospitals, how noncompliance can be remedied, and the consequences for exempt hospitals if it isn't,'' Griffith said.

''Assuming the Supreme Court does not toss out the entire health care reform law, 501(r) seems to be here to stay. Even if the law is tossed, 501(r) might be reenacted in a replacement health care reform law or stand alone legislation,'' he said. Questions surrounding the tax treatment of ACOs also will ''keep folks hopping,'' he said.

More Focused Investigations. Griffith also cited more prevalent and sophisticated enforcement efforts by IRS and other agencies that oversee exempt hospital compliance. ''Expect more, and more focused, investigations of potential violations, at least at the federal level, and expect novel theories and far reaching fishing expeditions.''

''Expect novel theories and far reaching fishing expeditions,'' from IRS.

GERALD M. GRIFFITH

Mayo, of SMU/Dedman, noted that PPACA also has important things to say about hospital charges, billing, and debt collection, although the provisions lack detail, Mayo said. ''The IRS should be filling in with its own interpretations this year, and hospitals will have to start planning in 2012 to be in a position to meet requirements that will kick in for most of them in 2013,'' he added.

Mayo also predicted that charity care, although not required by PPACA, is going to get a longer, harder look over the next three years.

With respect to state and local taxation of exempt hospitals, this issue will continue to percolate in states like Illinois and Ohio and is expected to spread to other states because of the serious and entrenched budgetary woes they face, board members said.

Griffith said he expects more property tax exemption challenges in 2012. ''State and local governments are hurting from a fiscal perspective in most areas and hospitals are often viewed as an attractive source of potential revenue given the size of their facilities and revenues,'' he said.

''Expect the challenges to spread from Ohio, Illinois and Wisconsin to other states in an attempt to move the focus to charity care rather than a broader view of what activities benefit the community as a whole,'' he said.

Increased Need for Tax Revenues. According to Foley & Lardner's Waxman, as life for municipalities and counties continues to get tougher, the need for tax revenues is ever increasing. ''Illinois has garnered a great deal of publicity in this area, but this effort is not one that is just in play in Illinois,'' Waxman said.

''Payments in lieu of taxes are increasing in amount in many jurisdictions as the method to hold off legislation or the imposition of mandates concerning the amount of charity care required to ensure and retain tax exempt status,'' he added.

Tuckman, of Advisory Health Management Group, agreed, that continued fiscal pressures on state and local governments will result in additional scrutiny of the tax-exempt status of many hospitals.

''As a result of demands from the credit markets as well as the recent favorable operating performance enjoyed by many market leaders, many nonprofit health care organizations have amassed considerable balance sheets,'' Tuckman noted.

''The existence of these assets that are not being utilized to support direct community based activities, along with an impending decrease in the number of uninsured under health care reform will certainly increase demands for increased financial contributions by nonprofit hospitals to support their charitable status,'' he said.

Mayo agreed, saying said there is no indication that local taxing authorities are losing their interest in challenging the tax-exemptions of hospitals. ''State and local governments' fiscal outlook is bleak and getting bleaker, and getting these properties back on the tax rolls is an ever more attractive goal for them to pursue,'' he said.

State AG Actions. Several board members said they expect to see an increase in the number of actions initiated by state attorneys general across a range of issues affecting tax-exempt hospitals. McDermott Will's Peregrine said he expects increased state attorney general efforts to challenge executive compensation arrangements perceived as either unreasonable or the byproduct of a flawed compensation process.

''They may cite invalid comparability data, conflicts in the compensation committee, lack of independence of the compensation consultant, or other concerns and may be emboldened by the current political and economic climate, and by actions New York and other states have taken to regulate perceived excessive compensation,'' Peregrine said.

They also are not burdened by having to overcome the rebuttable presumption of reasonableness that applies to IRS under IRC § 4958, he added.

Griffith also predicted that attorney general activism ''is likely to make a comeback in health care as hospital deals continue to flourish, especially deals that convert nonprofit facilities into for-profit ones or partner them with for-profits.''

10. Corporate Governance

Corporate governance remains a top health care issue for 2012 primarily because of the increased compliance and oversight responsibilities being placed on corporate boards and their members associated with participation in a health care delivery system that gets more complex and challenging every year, advisory board members said.

Executive compensation, fraud and abuse, quality monitoring and reporting, and conflicts of interests are just a few of myriad issues requiring an attentive and competent board, they said. With the threat of liability based on the responsible corporate officer doctrine a sobering reality, the stakes for lax board oversight are higher than ever, they added.

Loyola University's Blum said corporate governance is a critical issue for health care organizations, which must ensure they have board members who are up to the task. ''Health care boards will need to be responsive to the increasing complexities in the environments in which they operate and will be profoundly challenged by the expansive nature of regulatory mandates from both a conceptual and a compliance standpoint,'' he said.

More Prominence for Board. Hastings, of Epstein Becker, agreed, citing the rise and growth of ACOs and ACO-like entities as a development that will cause corporate governance to assume much more prominence. ''Under both the MSSP Final Rule and the NCQA accreditation guidelines, there are specific requirements applicable to the ACO governing body, including requirements as to the board's composition,'' Hastings noted.

''Add to that the ongoing evaluation of post-Sarbanes-Oxley and Dodd-Frank thinking and the significant quality measurement and reporting obligations being placed on health care providers and the ACOs they form and participate in, and you have a very robust and challenging governance dynamic,'' he said.

MaineHealth's Belmont noted that, as the 10th anniversary of the enactment of Sarbanes-Oxley approaches, corporate governance and related compliance responsibilities remain a high priority for health care providers.

Corporate governance and related compliance responsibilities remain a high priority for health care providers.

ELISABETH BELMONT

''Recent headlines reporting on high-ranking leaders of a public university and nonprofit charitable organization for failure to adequately address allegations of specific misconduct emphasize the need for health care providers to continually foster a culture of compliance,'' Belmont said. ''They must also have a process for actually following up on reported misconduct through effective whistleblower and investigative policies to reduce the risk of harm to individual victims and minimize the potential for monetary damages and reputational harm.''

''The attention given recent events suggests that the government and private claimants will increasingly target individual members of senior management or the board of directors who have knowledge of illegal activity within their organization but fail to act,'' she said.

  HLR ISSN 1064-2137

Peregrine, of McDermott Will, said corporate governance scrutiny, already heightened in the health care sector, will be affected in large part in 2012 by the resolution of the current highly visible scandals involving nonprofit organizations.

''To the extent the internal and external investigations of these scandals reach conclusions about the role of the governing boards, it is likely to have a broad impact on how regulators view the quality of nonprofit organization oversight,'' he said.

''Another significant governance issue in 2012 will be the increase in provider and health system efforts to streamline their corporate structure and governance model in an effort to increase efficiency, reduce costs of governance and system administration, and reduce the burden on voluntary directors,'' Peregrine said.

''These streamlining efforts will need to be balanced with the increasing importance of attentive oversight from governing boards, which could be compromised should board size be reduced to ineffective levels,'' he said.

''It is also likely that the business judgment and oversight of provider boards may come into question by regulators examining the reasons for organizational noncompliance with fraud prevention laws. More questions about 'where was the board?' are likely to be asked—particularly at the state attorney general level—when providers are required to pay large settlements to the government to resolve fraud charges,'' Peregrine said.

''One issue that combines governance and compliance will be the increased regulatory expectation that the board will assume much greater oversight authority with respect to quality of care matters, and the compliance implications of billing Medicare and Medicaid for substandard care,'' Peregrine continued. ''OIG can be expected to maintain a high profile in 2012 with respect to its expectations of the governing board in this regard.''

''Also expect closer state regulatory scrutiny of the board's business judgment in controversial merger and acquisition transactions, particularly in cross border transactions where charitable trust issues are raised with respect to allocation of direct and indirect charitable gifts and the flow of funds between affiliated institutions and transactions where legitimate questions are raised with respect to the extent of the board's diligence in evaluating strategic options, and in negotiating reasonable terms and conditions,'' Peregrine said.

***Lifespan* Decision.** ''2012 could also see a spillover impact of the *Lifespan* decision addressing fiduciary duties owed by parent organizations to subsidiary entities. This ruling, and an earlier Ohio state court ruling on similar issues, will work to increase the risk of destabilization in health care systems that were formed over the years through common parent mergers and affiliations,'' he said.

Sidley Austin's Raskin and Davis Wright Tremaine's Ross both said that DOJ's focus on ''responsible corporate officers'' will make the board's compliance with its oversight and approval responsibilities a particularly high priority in the board room.

According to Ross, both DOJ and the OIG will be looking for individuals to hold responsible for the misdeeds of their organizations. ''The responsible corporate officer doctrine or some variation of the same will be increasingly applied in an attempt to hold health care executives accountable for everything from kickback schemes and off label marketing, to billing errors,'' he predicted.

RegionalCare's Wall said that 2012 could see expanded oversight of nonprofit hospital governance. ''As investor owned health care companies face a range of governance and securities regulatory requirements from Sarbanes-Oxley to SEC requirements such as 'say on pay,' the IRS or possibly state attorneys general could decide that nonprofit hospitals should face comparable governance and compensation scrutiny,'' he suggested.

Honorable Mention

Professional Liability. Several board members said they expect to see changes in the professional liability landscape in 2012 as states, and perhaps even Congress, look to adopt tort reform left out of PPACA. Others said changes in health care delivery and the use of quality measures could affect the determination in malpractice cases of what constitutes the applicable standard of care.

Kanwit, of Stephanie Kanwit LLC, said ''2012 may be the year that the U.S. gets a national standard for professional liability in terms of medical malpractice reform, as it appears that many on both sides of the aisle would support fixing a broken, expensive system that currently doesn't benefit injured patients, help providers absorb lessons learned from alleged errors in care, or encourage adoption of evidence-based standards of care.''

''I predict that state legislatures will be struggling with tort reform in 2012.''

VICKI YATES BROWN

Brown, of Frost Brown Todd, agreed. ''In Kentucky, the issue of professional liability is predicted to be a significant issue in the 2012 legislative session because Kentucky has not adopted tort reform and because Congress did not address the issue in PPACA. I predict that state legislatures will be struggling with tort reform in 2012.''

Standard of Care. Belmont, of MaineHealth, said she thought professional liability could be affected by an evolution in the standard of care that is applied in malpractice cases. ''In order to meet the external quality benchmarks imposed by the federal government and commercial payers, health care organizations increasingly are implementing evidence-based clinical protocols that may serve to heighten the standard of care in medical malpractice actions,'' she said.

The availability of peer review materials in malpractice actions also could be affected by quality-based initiatives and collaborative ventures, such as ACOs, that emphasize a continuum of care by a group of providers and that utilize performance benchmarks and evaluations, she said.

''Health care organizations seeking to extend state peer review protections to include the review of physicians in the context of a broader system of care such as

ACOs will face an increased likelihood of losing the peer review privilege in malpractice suits and other court proceedings since many state peer review statutes are highly restrictive in their protections—protecting only proceedings involving physicians as opposed to other providers; only the records of formal peer review proceedings as opposed to broader forms of peer oversight; and only in-hospital peer review,'' Belmont said.

Life sciences advances and use of personalized medicine will also affected malpractice claims, Belmont said. ''As performance metrics, payment, outcomes, incentives, services and treatments address differences in patient needs and preferences and as the focus of health systems shifts from reactive medicine to prevention and cure, personalized medicine will play an increasingly important role.''

Belmont also predicted the use of stem cell therapy and other new technologies in treating patients will create new types of medical malpractice claims. ''For example, claims may include complaints that physicians did not tailor therapy to appropriate analysis of the patient's genotype,'' she said.

''Today, complications arising from the side effects of medication are the subject of a medical malpractice claim. When the promise of pharmacogenomics and genotypically-based personalized medicine becomes a reality, the standard of care concerning the prescription of certain medicines likely will include the requirement that the patient's genotype be factored into the therapeutic decision,'' Belmont said.

Mobility/Telemedicine. Several board members also predicted telemedicine and mobility within the health care delivery system—for physicians, hospitals, patients—made possible by technology and changed models for accessing care will continue to influence and reshape health care in 2012.

Telemedicine ''will require states to proactively redefine their licensing laws to accommodate these technologies.''

ERIC A. TUCKMAN

According to Tuckman, of Advisory Health Management Group, ''innovations that are now ready for implementation in the field of telemedicine will require states to proactively redefine their licensing laws to accommodate these technologies.'' Meanwhile, ''large health plans are implementing new ways to access health providers such as virtual online doctor appointments and the expansion of retail clinics utilizing physician extenders that will challenge traditional notions of professional licensure and scope of permissible practice,'' he said.

''These advances will also require the redefinition of permissible reimbursement practices to enable less costly modes of patient care to be delivered, especially to the elderly in the post acute setting,'' he added.

Burde, of Howard Burde Health Law, said he sees mobility as a key issue going forward. ''This theme reflects the increasing ability to provide care in locations remote from hospitals and physician offices. Technologies which enable the sharing of diagnostic test results, digital images, physician notes, not to mention EHRs and prescriptive information, also enable the provision of care in lower acuity sites as well as in remote locations,'' Burde said.

''Patients are more able to remain in place rather than travel to care. This trend toward mobility will have vast implications for reimbursement, facilities, and physician offices. Already it is enabling the growth of urgent care centers, consumer-based retail care and employer based clinics,'' he added.

CMS Telemedicine Regulations. Fulbright & Jaworski's Kadzielski pointed to the new CMS regulations governing telemedicine and said they contain both good and bad news for hospitals. ''The good news is that telemedicine services are now viewed as acceptable, and the credentialing of individual providers is more relaxed,'' he said.

''The bad news is that telemedicine entities—that is, non-hospital providers like radiology groups—do not have rigorous standards for credentialing individual providers on a regular basis, and therefore written agreements with such entities need to be very carefully drafted to protect the facilities that use their telemedicine services,'' he continued.

''From a medical staff organizational standpoint, telemedicine ushers in a new era of individual providers who hold telemedicine privileges but are not medical staff members, a concept that will be difficult for some to grasp. Turnover in individuals with telemedicine privileges will also create more credentialing challenges as well as more liability exposure for hospitals,'' Kadzielski said.

Belmont predicted that mobile health applications will become increasingly prevalent in 2012. Such applications include (i) incorporating patient-generated digital health data into the EHR (for example, through the monitoring of a chronic condition at home); (ii) including digital provider-generated data from video consults, imaging and other services in the EHR; (iii) recording a care plan for patients with high-priority health conditions; (iv) encouraging the use of online self-management tools for patients with high-priority health conditions; and (v) incorporating other telehealth uses into structured data requirements, she noted.

''The use of mobile health applications presents myriad legal issues for health care organizations to wrestle with in 2012 including, for example, privacy and security issues, regulatory and compliance issues, and potential medical malpractice liability,'' Belmont said.

BY PEYTON M. STURGES AND MARY ANNE PAZANOWSKI

  HLR ISSN 1064-2137