Bloomberg BNA

BNA's
Health Law Reporter™

Outlook 2016

Provider Realignment, Fraud and Abuse Head List of Top Health Law Issues for 2016

The need of providers to collaborate to meet the Affordable Care Act's goals of improving access to high quality health care at lower costs made hospital/physician alignment the top health law issue for 2016, according to the editorial advisory board of *Bloomberg BNA's Health Law Reporter*.

For the second year in a row, the emphasis on coordinating patient care—driven by new reimbursement models of both government and commercial payers—will lead to more mergers, affiliations and cooperative endeavors in the health-care industry, they said. ''The reality is that everything that is being contemplated by health reform and health system transformation is completely dependent upon physician and health system alignment,'' Howard T. Wall III, with RegionalCare Hospital Partners Inc., Brentwood, Tenn., told Bloomberg BNA.

Fraud and abuse concerns, driven in part by changing care delivery patterns, innovative provider relationships and challenging—and often baffling—legal constraints, made this issue the second most significant health law issue for 2016, board members said. ''There are so many ambiguities in the Stark law and Anti-Kickback Statute (AKS) that even health-care facilities and companies that think they are compliant may be targets for major compliance and False Claims Act (FCA) exposures,'' Gary W. Herschman, with Epstein Becker & Green PC, Newark, N.J., said

Health information and technology ranked third this year, although board members said this area poses some of the most perplexing challenges. From the cost and complexity of health information technology adoption to the substantial and seemingly unavoidable risks of data breaches, this compliance focal point will demand significant attention by providers—from the staff level to board rooms—this year, they said.

Board members ranked Medicare, given its critical role as most providers' main revenue source and the driver of new reimbursement models focused on care coordination, quality and cost, fourth, followed closely by antitrust. Board members cited the legal implications of maintaining competition in health-care markets in the face of unprecedented realignment and collaboration pressures as a substantial legal compliance issue for 2016.

The ''trickle up'' effect, wherein corporate leadership and directors are expected more than ever to understand and manage the full array of compliance challenges facing their organizations, makes corporate governance sixth on this year's Top Ten list. Health-care quality was ranked seventh by board members as an issue that permeates all other health law issues. It ranked just ahead of health plan regulation, a huge area of concern for both providers and consumers.

Telemedicine, which received enough votes this year to be ranked separately, and Medicaid, which is a hot political issue on which financial stability of providers and the health care of millions of indigent families depends, rounded out the Top Ten list. Taxation received honorable mention, based in large part on the increasingly real prospect that more nonprofit health-care providers will be faced with state and local tax bills.

Health Law Reporter's Top 10 for 2016

1. Compliance challenges of responding to unprecedented **hospital/physician alignment** pressures make this the top issue for the second year in a row.
2. **Fraud and abuse** remains a huge practice focus for nearly every health lawyer.
3. Concerns over implementation costs and data breaches make **health information and technology** a top issue.
4. **Medicare** payment and audit regimes continue to drive health system change.
5. Realignment pressures and focused enforcement scrutiny keep **antitrust** law compliance key.
6. Overall provider compliance and individual liability risks demand substantial attention to **corporate governance**.
7. **Health-care quality** remains the guiding principal of health system reform.
8. Regulatory uncertainties facing commercial payers and new provider payment methods elevate **health plan regulation** concerns.
9. The growing field of **telemedicine** provides new challenges for providers and regulators alike.
10. **Medicaid** program expansion and states' adoption of managed care to meet recipient needs continue.

 ISSN 1064-2137

1: HOSPITAL/PHYSICIAN ALIGNMENT: Affiliation-Driven Concerns Lead Top Ten

Hospital/physician alignments, along with several other types of transactions, including health-system consolidations and mergers and acquisitions (M&A) throughout all segments of the health-care industry, made 2015 a banner year for affiliations—and the trend is expected to continue and grow through 2016, advisory board members said.

Following 2015's flurry of alignment activity, ''2016 promises to be another record year,'' according to Dawn Crumel, with Sheppard, Mullin, Richter & Hampton LLP, Washington. She predicted that the ''high level of health-care transactional activity'' won't be slowing down any time soon.

John R. Washlick, with Buchanan Ingersoll & Rooney, Philadelphia, agreed, saying that each ''year seems to set a record over the previous year, and 2015 was no exception.''

Alignment is ''a real game changer for health care'' because it provides incentives for hospitals and physicians to work together to share reimbursement, Mark A. Kadzielski, with Pepper Hamilton LLP, Los Angeles, said.

Transactions Involving Physicians. The trend toward alignment began several years ago, with hospitals and health systems acquiring physician practices. Rather than slowing down, this trend could accelerate, according to Phil Zarone, with Horty Springer & Mattern PC, Pittsburgh. Gary Herschman suggested that even physicians who previously ''stayed on the sidelines'' may begin aligning with hospitals and health systems.

Alignment is ''a real game changer for health care'' because it provides incentives for hospitals and physicians to work together to share reimbursement.

MARK A. KADZIELSKI, PEPPER HAMILTON LLP, LOS ANGELES

Gerald M. Griffith, with Jones Day, Chicago, told Bloomberg BNA that payment model changes, along with the ''increased cost and complexity of operating a private practice'' will lead more physicians to seek out alignments that will provide job security and a more reliable source of income.

Howard Wall said providers will be challenged to adopt a ''multi-disciplinary, team-based, patient-centered approach to care and transform traditional medical staff models to reflect the new ways of delivering care,'' all designed to lower costs and improve quality.

The ''struggle is how to create economic models, such as traditional employment, co-management or gainsharing—to name a few—that create economic incentives to encourage behaviors that will improve patient safety and lower costs without running afoul of the AKS, the Stark law or other laws,'' Wall said.

At any rate, the life expectancy of a small physician group is limited, even in rural areas, Kadzielski said. Independent physicians and hospitals are ''an endangered species,'' he added.

According to Jack A. Rovner, with The Health Law Consultancy, Chicago, alignments follow ''two parameters, each with important implications for health-care delivery.'' Hospital acquisitions of physician practices are seen as ''primarily a defensive move to preserve the hospital business model, lock in physician referrals and retain or expand extra 'facility fee' revenue.''

The second model encompasses ''clinically-integrated physician-driven alignments,'' Rovner said. In this model, physicians remain independent but collaborate ''resources, oversight and management to improve care quality, coordination and convenience.''

Facility Fees May Slow Alignment. One development that could slow down this trend is the exclusion of off-campus outpatient departments from reimbursement under Medicare's outpatient prospective payment system (OPPS), Washlick told Bloomberg BNA. Hospitals might become reluctant to acquire practices that no longer qualify for provider-based status, he said. To qualify, a practice would have had to have been located on, or relocated to, a hospital campus before Nov. 2, 2015, he said.

Legislation implementing this rule was ''designed to result in a more level playing field between hospitals and physicians providing medical services'' who are similarly situated to hospitals but don't receive the ''special treatment afforded hospitals under provider-based rules,'' Washlick said.

Rovner said the elimination of hospital facility fees on outpatient procedures covered by Medicare, especially if commercial payers follow suit, ''significantly may reduce'' incentives for alignments.

Legal Issues. Hospital/physician alignment greatly impacts many issues, including ''deciding whether to use the medical staff peer review process or the HR process when quality or behavioral concerns are raised,'' Zarone said. Hospitals that employ physicians also have liability risks under employment discrimination laws, he said.

Katherine Benesch, with Benesch & Associates LLC, Princeton, N.J., added that issues may arise over the effect an alignment can have on a physician practice's agreements with insurers. Does the hospital ''assume the physicians' contract for reimbursement with the plan and, if so, at what rates?'' Benesch also asked whether a hospital that has a separate contract with the same insurer can charge a higher rate for physician services provided at the hospital than the physician previously charged for office-provided services.

Contract language addressing these issues ''often muddies the waters significantly,'' Benesch said.

Vickie Yates Brown, until recently with Frost Brown Todd LLC, Louisville, Ky., told Bloomberg BNA that the traditional medical staff model for hospitals is ''in a state of flux'' due to alignment changes. The new year ''will likely require physicians and hospitals to examine the implementation of new models and contractual relationships that protect all parties and better address these changing dynamics,'' she said. Brown provided her thoughts before she was appointed Secretary of Kentucky's Cabinet for Health and Family Services.

As the medical staff model gives way to the employed physician model as a result of alignments, physician

  HLR ISSN 1064-2137

compensation issues could arise, Kim H. Roeder, of King & Spalding LLP, Atlanta, said.

The corporate-practice-of-medicine doctrine also could prove to be a challenge in states where the doctrine still thrives, Kadzielski said.

Kadzielski also told Bloomberg BNA that, in the rush to align, few people are ''paying attention to details.'' That, ultimately, will give rise to many legal issues, including how consolidated systems, providers and payers will manage their combined information so as not to violate the Health Insurance Portability and Accountability Act (HIPAA).

He also noted that negligent credentialing issues could arise. With hospitals anxious to align with physician practices, they might not be doing a thorough job of vetting the physicians, he said.

In short, in the rush to get an alignment done, the liability issues are being pushed ''down the road,'' Kadzielski said. These issues will be ''percolating,'' possibly for months or years, and managing them after-the-fact will be ''time-consuming and costly,'' he said.

It is important for ''hospitals and physicians to figure out the next steps in the event they need to unwind their alignment arrangements.''

MICHAEL F. SCHAFF, WILENTZ, GOLDMAN & SPITZER PA, WOODBRIDGE, N.J.

Thomas Wm. Mayo, with SMU/Dedman School of Law, Dallas, called other ''spin-off issues'' associated with new alignment strategies, including antitrust, governance and fraud and abuse concerns, ''daunting.''

Evolution of New Alignment Approaches. As for the future, Herschman said that many arrangements entered into three-to-five years ago are coming up for renewal. It is not clear whether most of those arrangements will be renewed or, if they are, on what terms, he said.

''There are now many more national and regional strategic and private-equity backed companies acquiring—and looking to acquire more—physician practices, and, thus, physician groups now have alternative options for the future.''

Michael F. Schaff, with Wilentz, Goldman & Spitzer PA, Woodbridge, N.J., said that, in 2016, it will be important to review the lessons learned from both successful and unsuccessful alignments. ''These lessons can be helpful when structuring new ways for physicians and hospitals to align their interests.'' It is also important, he said, for ''hospitals and physicians to figure out the next steps in the event they need to unwind their alignment arrangements.''

J. Mark Waxman, with Foley & Lardner, Boston, warned that ''we do not know what the delivery system will look like even in the short term.'' While some experts ''have speculated about the ability to sustain the current pace of M&A activity, with health plan mergers, hospital mergers and affiliations, and physician group acquisitions and consolidations, the system is clearly in flux.'' Where it will end up ''is not clear,'' Waxman said.

Consolidations, M&A Activity. The consolidation trend will have an effect on medical staffs, Lowell C. Brown, Arent Fox, Los Angeles, said. As providers become more clinically integrated, ''hospital medical staffs and their counterparts in similar organizations (like ambulatory surgical centers and large medical groups) will continue to become less influential regarding policy and business decisions made by hospitals and health systems.''

Not all health-care industry transactions are taking the form of traditional mergers and acquisitions. Washlick said new ''market models are emerging where hospitals, health systems and physicians are combining to form clinically integrated networks.'' By doing so, they are able to preserve their independence, their governance models, charitable missions and corporate operations.

At the same time, many of these providers, including ''single-site community hospitals and small hospital systems, are struggling to maintain independent governance and continue their community commitment,'' Washlick said.

Griffith noted that ''financially troubled providers unable to keep pace with the changing payment models and required investment will get swallowed up by larger systems or drift into bankruptcy.''

''Consolidation in virtually every segment of the health-care industry is growing,'' Kirk J. Nahra, Wiley Rein LLP, Washington, said. Realistically, the country may be left with ''only a small number of competitors in many major market segments.'' The government ''will be faced with substantial challenges on how to handle this growing concentration in many of these key markets,'' he said.

2: FRAUD AND ABUSE: Stepped-Up Enforcement Efforts Expected in 2016

A perennial concern for health-care lawyers, fraud and abuse enforcement is near the top of the list of health law issues for 2016 according to advisory board members.

They cited not only an increase in the volume of enforcement actions under the Stark law, the FCA and the AKS, but also a provision in the recently signed Bipartisan Budget Act of 2015 allowing for increased civil penalties in fraud and abuse actions.

Pace of Enforcement Actions. According to Robert L. Roth, Hooper, Lundy & Bookman PC, Washington, ''we seem to be entering a year where enforcement actions will overshadow regulatory issues.''

Jack Rovner said that ''government enforcement and whistleblower actions should continue unabated or indeed, with increased vigor.'' Government wins in cases such as *United States ex rel. Drakeford v. Tuomey Healthcare Sys. Inc.* (D.S.C., No. 3:05-cv-2858, *settled* 10/16/15), ''expand the scope of the federal fraud and abuse laws and FCA coverage.''

The settlement in that case helped the hospital avoid a $237 million damage award that had been confirmed by the U.S. Court of Appeals for the Fourth Circuit. The award was based on a jury's finding that the hospital engaged in a scheme to pay physicians for referrals.

Gary Herschman said that ''the *Tuomey* decision and other recent major settlements demonstrate that increased enforcement is further snowballing, with no end in sight.''

Michael Schaff agreed, pointing to the fact that the Health and Human Services Department created a new litigation team within the Office of Inspector General to pursue actions under the FCA and AKS, following a 2015 OIG fraud alert ''that warned physicians to carefully consider their compensation arrangements so as not to incur penalties by violating the AKS.''

Increased Civil Penalties. The Bipartisan Budget Act will require federal agencies to impose higher civil penalties, a ''development that should raise significant concern within the health-care industry for a number of obvious reasons,'' said Sanford V. Teplitzky, with Ober Kaler, Baltimore.

In particular, Teplitzky expressed concern with the law's mandate to adjust the civil penalties for inflation and to implement a ''catch-up'' to reflect Consumer Price Index increases that have occurred since 1999—the last time the Department of Justice increased the FCA penalties.

Acknowledging that the OIG or DOJ rarely has imposed the maximum penalties available to them, Teplitzky said that ''the pure mathematical calculation of penalties will no doubt serve to restrict even further the realistic ability of health-care providers to get their day in court.''

''The pure mathematical calculation of penalties will no doubt serve to restrict even further the realistic ability of health-care providers to get their day in court.''

SANFORD V. TEPLITZKY, OBER KALER, BALTIMORE

He added that ''this is particularly true under the FCA where the courts are required—upon confirmed proof of the submission of false claims—to impose at least the minimum penalty amount per claim.''

Individual Responsibility. ''The year of the whistleblower, 2015, is a precursor to 2016, the year of individual responsibility,'' Dawn Crumel said.

She pointed to the memo released by Deputy Attorney General Sally Yates in which she announced a new emphasis on holding corporate executives individually accountable for corporate wrongdoing. The memo will require increased focus on individuals within health-care providers' compliance programs, Crumel said.

She added, ''given the potential for exclusion of individuals, the Yates memo has a particular effect of having in-house counsel hiring more outside counsel to represent individuals as investigations of potential compliance issues occur.''

Compensation Arrangements. Howard Wall warned of increased compliance requirements that providers must consider before entering into compensation arrangements that might trigger a fraud investigation.

''It no longer seems adequate to obtain third-party opinions on issues like fair market value and commercial reasonableness at the outset of an arrangement,'' he said. Now, ''the standard seems to suggest the need for ongoing monitoring and modification of the arrangement in light of facts and circumstances.''

Wall added, ''providers who believe that they can take comfort in a compensation arrangement that was fair market value, set in advance and did not take into account the volume or value of referrals may be surprised as theories of health-care prosecutions and investigations continue to evolve.''

John Washlick pointed to one bright development for providers worrying about compliance. ''Recent proposed amendments to the Stark regulations published by the Centers for Medicare and Medicaid Services under the 2016 Physician Fee Schedule should reduce the number of self-disclosures under the Stark self-referral disclosure protocol (SRDP) for a number of technical violations involving, in particular, what constitutes a written agreement, expired terms and unsigned agreements.''

Teplitzky agreed. ''While CMS continues to underestimate the time and expense of preparing a disclosure, its apparent willingness to make changes in the Stark exceptions and to the SRDP is a positive development that should improve both the experience and the outcome of Stark voluntary disclosures,'' he said.

60-Day Rule Guidance. Mark Waxman said he hopes that 2016 will bring additional guidance from the enforcement agencies to assist providers in avoiding fraud investigations. ''Unless there is additional governmental guidance on such things as the 60-day repayment obligation, or the scope of the exemptions in the face of risk-sharing arrangements that do not quite fit in the safe harbors, the exposure to an unforgiving environment will only continue to go up,'' he said.

He added, ''this threatens a great number of arrangements that do not drive up cost, or result in duplication, but may involve closer patient caring relationships.''

The 60-day rule requires a provider to disclose and return an identified overpayment within 60 days or risk exposure to ''reverse'' FCA liability.

According to Douglas Ross, with Davis Wright Tremaine, Seattle, the first court case to interpret the 60-day rule, *Kane v. HealthFirst, Inc.* (No. 11-2325, 2015 BL 249012 (S.D.N.Y. Aug. 3, 2015)), ''adopted a definition of 'identify' that the judge conceded was impractical—one that hospitals simply will not be able to satisfy in many instances.''

Teplitzky agreed, saying that ''the real life problem is that many of the situations that may lead to an overpayment—for example based on technical or procedural noncompliance with Stark—are complex and heavily fact-dependent.''

He said that, as a result, there is a ''real potential that significant effort and expense will be required, even where there is absolutely no abuse or harm to the federal programs or, more importantly, to their beneficiaries.''

HHS is expected to release the final 60-day rule sometime in February, according to its regulatory agenda released in November.

New Delivery Systems. Teplitzky pointed to recent fraud and abuse waivers provided to accountable care organizations (ACOs) operating within the Medicare Shared Savings Program as evidence that the government is looking to encourage these new delivery systems and collaborative models.

  HLR ISSN 1064-2137

''CMS and Congress continue to encourage the development of new and alternative health-care delivery systems that have the potential to improve quality of care and reduce costs,'' he said.

However, Teplitzky noted a long-standing concern that ''the fraud and abuse laws were enacted during a time when the health-care delivery participants were expected to stay in silos in which each played its own role and billed for its own services.''

With the rise of ACOs and other collaborative practice models, Teplitzky said that fraud and abuse waivers for these models are encouraging and show that the agencies are taking a closer look at how they can remove burdensome and unnecessary barriers to developing these systems.

3: HEALTH INFORMATION AND TECHNOLOGY: Data Security, Rapid Change Pose Risks

Health information and technology ''needs to be high on the list of provider risks and opportunities,'' Richard Raskin, with Sidley Austin LLP, Chicago, told Bloomberg BNA. The risks include data breaches, HIPAA compliance, and failures to meet market demands, while changes in technology, like the development of Big Data, ''hold out the prospect of improved care and enhanced reimbursement,'' he said.

Interoperability. The topic of health information and technology ''encompasses many different and somewhat unconnected topics, each important in its own right,'' Kirk Nahra said. The first of these topics is interoperability.

''Interoperability is a big thing,'' Kim Roeder said. ''Determining how systems can share data in a meaningful way is taking up a tremendous amount of time and resources,'' she said.

''It's become painfully evident in working with clinically integrated networks (CINs) and other types of alignment structures that one of the most important factors and biggest budget items is information technology,'' Roeder said. Getting all the systems used by various members of a CIN or ACO to work together—without violating HIPAA—is challenging.

Elisabeth Belmont, with MaineHealth, Portland, Maine, also sees interoperability as a big issue because a failure to achieve interoperability raises the risk of losing meaningful use incentive payments, Stark law exceptions and AKS safe-harbors. T.J. Sullivan, with Drinker Biddle & Reath LLP, Washington, added that there reportedly ''has been some progress toward interoperability, but the federal government will have to keep the pressure on to keep efforts moving.''

Big Data and Nontraditional Data Sources. New and nontraditional data sources also may prove challenging, Nahra said. The health-care industry is finding ''all kinds of new data that can be useful, but the legal/regulatory structure simply is not keeping up at this point,'' he said.

The ''overall issue in 2016 will be what the rules are for all of this new data, aside from legal and regulatory concerns,'' Nahra said. Nearly every company that deals with health-care information ''will need to develop an appropriate data strategy that balances business and health-care opportunities with the evolving legal and regulatory structure,'' he added.

Belmont also noted concerns about the use of alternative sources of data. Wearable technologies that measure health data, like Fitbit, ''can provide researchers access to vast stores of biometric data'' that they can use to test hypotheses and treatment outcomes, she said. Additionally, government payers have ''vast stores of billing data that can be mined to promote high quality care and prevent billing fraud.'' Hospitals and other big providers ''increasingly are using big data to assist with treatment decisions,'' Belmont said.

Given the increasing focus on big data, ''health-care providers should ensure that their 2016 compliance programs incorporate data governance plans with respect to decisions on how big data will be used, shared or released,'' Belmont said.

Cybersecurity and Data Breaches. As more and more health records are digitized, ''the potential for massive hacks—not to mention the everyday, garden-variety data breach—becomes greater and greater,'' Tom Mayo said. Cybersecurity is ''the 800-pound gorilla in the room,'' he said.

''Cyber is a confusing and overly dramatic buzzword, but it is clear the health-care industry faces major threats to its systems and operations, relating to both the protection of personal data and the safe and efficient operation of the health-care system,'' Nahra said. A cybersecurity law recently passed by the Senate carves out the health-care industry for ''special attention,'' Nahra noted.

Cybersecurity is ''the 800-pound gorilla in the room.''

THOMAS WM. MAYO, SMU/DEDMAN SCHOOL OF LAW, DALLAS

''Cybersecurity is more important than ever in the health-care setting,'' Mark Kadzielski said. Between 2010 and 2014, 37 million health-care records were exposed through data breaches, and in the first part of 2015 alone, nearly 100 data breaches led to the disclosure of more than 99 million health-care records, he said. Thus, ''proactive cybersecurity programs are essential for health-care providers to avoid, or at least minimize liability associated with data breaches. ''Proper staff training to avoid and respond to cyber attacks will help build the needed culture of cybersecurity in health-care organizations,'' he said.

Sophisticated hackers and cybercriminals pose the ''primary security threats for health-care organizations today,'' said Reece Hirsch, with Morgan, Lewis & Bockius LLP, San Francisco. Michael Schaff agreed. He said that HIPAA compliance is ''rapidly becoming a means for health-care providers to protect their very existence.'' But Hirsch warned that ''mere compliance with the HIPAA Security Rule is not sufficient if current cyber risks are not being taken into account.''

Dawn Crumel advised that health-care organizations ''should have multiple layers of defense and frequently assess their risk to ensure the security of protected health information.''

Kadzielski highlighted the cost of cyber breaches, noting that the price is in the ''billions of dollars'' once the damages paid to patients, penalties paid to federal

and state regulators and the costs of employing consultants to find and repair breaches are factored in.

The ''expense of addressing a data breach is enormous,'' Gerry Griffith told Bloomberg BNA, adding that the ''potential exposure to third parties,'' including patients and government regulators, ''is potentially even more staggering.''

Employee Data Breaches. Less sophisticated, but of just as much concern, are privacy breaches caused or perpetrated by health-care workers. Katherine Benesch said ''confidentiality remains a subject to sloganeering on wall posters but still is not internalized by health-care workers and hospital employees.'' Those employees ''need to understand what 'confidentiality' really means,'' she said.

Benesch also said health-care workers may become confused by the sheer amount of information available to them. Health-care providers must ''become more proficient in privacy protections and the appropriate use of confidential data and related technologies to care for patients,'' she said.

John Washlick expressed concern that efforts to stop data breaches ''will force providers to divert resources away from ensuring the physical safety of patients to safeguarding patient data.''

Focus of In-House Counsel. Health information and technology issues are just as important, if not more so, to in-house counsel. Belmont listed several issues she will be watching in 2016, including the ''increased focus on the safe design, implementation and use of health IT to promote patient safety.'' She said the *Health IT Safety Center Roadmap*, released by the Office of the National Coordinator for Health Information Technology in July 2015, provides a path for progress in the field of health information technology-related patient safety.

Electronic health information blocking also will be a thorny issue because states have begun looking into whether such practices are being used as a tool by health systems to coerce physicians to join their networks. On the other hand, prohibitions on information blocking have ''the potential to create conflict with patient authorizations, proprietary rights and breach notification obligations.'' The rules also possibly may conflict with laws requiring more stringent protection for certain patient information, including mental health and HIV records, Belmont said.

Hirsch added that the ''long-delayed HIPAA Phase 2 audits will begin in early 2016.'' While the odds of particular organization being audited appear to be ''fairly low,'' the Phase 2 audits likely will ''provide important insights into future Office for Civil Rights enforcement initiatives.''

4: MEDICARE: Changes to Reimbursement, Alternative Payment Methods

Although Medicare is always a top ten health law issue, 2016 will feature new challenges involving the continuing evolution of reimbursement regimes, advisory board members told Bloomberg BNA. Questions in the coming year also will revolve around the number of baby boomers becoming Medicare-eligible and program solvency, they added.

Issues will include the implementation of the new Merit-Based Incentive Payment System (MIPS), required by the Medicare Access & CHIP Reauthorization Act of 2015 (MACRA), the adoption of a new medical coding set—the International Classification of Diseases, 10th Revision (ICD-10)—and the continued growth of ACOs and alternative payment methods.

Changes to Reimbursement. According to John Blum, with Loyola University Chicago Institute for Health Law, ''Medicare is never far from the top of the list, and big pressures exist to meet the secretary's goal to dramatically expand reimbursement based on value.''

He cited the January 2015 announcement from HHS that, by the end of 2016, it will link 30 percent of Medicare reimbursements to the quality and value metrics in the MIPS.

''Medicare is never far from the top of the list, and big pressures exist to meet the secretary's goal to dramatically expand reimbursement based on value.''

JOHN BLUM, LOYOLA UNIVERSITY CHICAGO INSTITUTE FOR HEALTH LAW, CHICAGO

Elisabeth Belmont agreed, saying, ''in 2016, there will be an increased focus by health-care providers on meeting the requirements of this new payment system.''

ACOs. According to Gerry Griffith, ''Medicare remains the largest payer for most full service hospitals and an important payer for many physician practices, but the big stories here will relate to CMS going all in on ACOs and other alternative payment models.''

''As the payment system changes, so will CMS' manner of oversight,'' Griffith added.

Kim Roeder said that the alternative payment program is a ''very ambitious project for CMS,'' particularly because the results of the demonstration programs were mixed.

''The programs—like ACOs and clinically integrated networks—resulted in savings for the government, but the results for providers were mixed,'' she said.

''If there is an aggressive movement toward alternative payment systems, then it makes no sense to limit the systems to Medicare. There needs to be across-the-board change,'' Roeder added.

She also noted that in the most recent Stark rules, the agency declined to offer guidance on alternative payment systems and how they relate to the Stark law and MACRA. Guidance may be delayed for up to two years after the required reports to Congress on gainsharing and fraud and abuse in the ACO context, she said.

ICD-10 Grace Period to Expire. Advisory board members also pointed to the newly implemented ICD-10 as an issue that will plague Medicare providers in the coming year.

CMS gave providers a 12-month grace period from the coding set's original Oct. 1, 2015, implementation date, but some are still having difficulty adapting to the change.

Michael Schaff told Bloomberg BNA that ''despite delays in implementation and backlash from providers,

   ISSN 1064-2137

CMS reports that the initial transition to ICD-10 has been smooth.''

He added that ''providers will need to continue to work through growing pains related to this new, more detailed coding system in 2016.''

He noted that the CMS has vowed to remain flexible in reviewing coding issues and has developed numerous resources to assist providers in proper submissions, but ''whether Medicare will continue to be this flexible and helpful remains to be seen in 2016.''

Other Concerns. Solvency remains a concern for Medicare. Howard Wall said that the program's ''long term fiscal solvency will be on the agenda of the next president, and the next Congress and any budget reform efforts led by House Speaker Paul Ryan will likely target Medicare spending as a piggy bank to fund other programs or cut the deficit.''

As Jack Rovner said, ''the baby boomers are entering their Medicare years at rapidly increasing numbers, so political pressure will grow for better and affordable Medicare coverage backed by assured Medicare solvency.''

As an example, he cited the recently signed budget act, in which ''Congress avoided the big 2016 Medicare Part B bump in hopes of evading a political backlash from irritated senior voters.''

But Mark Kadzielski sounded a word of warning, saying that ''funding Medicare is a significant financial commitment of the federal government, and given the demands from constituents to cut or freeze taxes, politicians have their work cut out for them.''

Meanwhile, Vickie Brown focused on the increased costs expected by Medicare beneficiaries in the coming year.

''Most Medicare beneficiaries will pay significantly higher costs in 2016,'' she said, pointing to expected higher premiums for both Medicare Advantage and Medicare Part D plans.

''In addition, there will be fewer prescription drug plans to choose from in 2016, more out-of-pocket costs, higher deductibles and other cost-sharing requirements that will increase costs to Medicare beneficiaries in 2016,'' she said.

Bob Roth pointed to the implementation of the ''site neutrality'' provision of the Bipartisan Budget Act as ''the biggest Medicare issue at the moment for providers.''

The provision, which prohibits reimbursement under the current Medicare OPPS for services performed in off-campus facilities, is expected to lower overall Medicare spending but also could reduce the instances of hospitals opening or acquiring new off-campus outpatient facilities, he said.

Roth expressed interest in seeing how CMS implements the provision in the coming year as well as ''how quickly CMS does something to clarify the many open questions with implementation.''

5: ANTITRUST: Are Transactions Affecting Competition?

As the transactions activity has heated up in the health-care industry, so too has enforcement activity by the federal and state governments.

''As a result of the surge of M&A and other strategic affiliations, antitrust is a serious consideration'' when determining whether transactions can occur in the first place, according to John Washlick. The Federal Trade Commission and state agencies are very interested in the hospital consolidation trend and will challenge any merger or acquisition they view as reducing patient options, he said.

''The FTC and the DOJ's Antitrust Division were busy in 2015 reviewing a number of proposed acquisitions and mergers.'' They even ''rejected a few,'' Washlick said. ''Heightened scrutiny is expected in 2016 as industry consolidation continues among and between health systems, physician practices and payers,'' he added.

Jack Rovner agreed but warned that ''enforcement resources will be challenged to keep up with the industry's consolidation pace.''

''As a result of the surge of M&A and other strategic affiliations, antitrust is a serious consideration.''

JOHN WASHLICK, BUCHANAN, INGERSOLL & ROONEY, PHILADELPHIA

The ''antitrust agencies will continue to have plenty of potential cases to choose from, possibly including the first retrospective reviews of ACOs,'' Gerry Griffith said.

Mark Waxman told Bloomberg BNA he believes the ''drive to integrate will face increasing counter pressure'' in 2016 due to government enforcement efforts. He said that a ''drive initiated by payers through a push for narrow and tiered networks might survive scrutiny but, even in that case, antitrust exposure in a particular market may create real counter pressure,'' he said.

Dawn Crumel pointed to a complaint filed by the FTC opposing a proposed West Virginia hospital merger, and the agencies' joint statement to the Virginia Certificate of Public Need Workgroup, as evidence that the FTC will continue its involvement in state efforts to regulate competition. In the joint statement, the agencies said certificate-of-need requirements are anticompetitive.

Howard Wall also sees a continued increase in activity by the FTC and DOJ. He asked whether health-care market consolidation, which is ''extremely decentralized'' on the provider side, reduces competition and increases costs, or whether ''consolidation, standardization and dramatic cost reductions are the only way to achieve the long-term goals of higher quality and lower cost.''

Katherine Benesch, however, pointed out that ''antitrust enforcement by the federal government has been selective.'' The government has issued waivers ''to encourage consolidation and new cooperative initiatives blessed by the ACA.''

Still, ''hospitals and proposed hospital mergers continue to be attacked for restraint of trade, anticompetitive behavior and foreclosing price competition in specific markets,'' she said.

Richard Raskin said that private antitrust litigation also will be ''hot,'' with a particular emphasis on the alleged exclusionary practices of providers and manufacturers with large market shares.

Insurer Mergers. T.J. Sullivan said the ''pending insurance company mergers will be important to watch, as hospitals and physician groups like the American Medical Association express concerns about the effects of further payer consolidation, and the DOJ tries to weigh the effects on competition and consumers.''

Doug Ross questioned whether the Antitrust Division will ''step up and oppose the pending insurer mergers with the same vigor the FTC reserves for hospital mergers.''

6: GOVERNANCE: Resurgence in 2016

Governance issues involving health-care stakeholders always have been important, but they seem to be taking on even greater significance in 2016, board members said. The government's more aggressive enforcement of fraud and abuse laws and a perception that directors should be doing more to ensure compliance to avoid now sky-high damages awards and settlement costs lead the reasons for their resurgence.

Increased transactions activity, too, is putting more pressure on boards to ensure their organizations are in a good position to align with other companies and providers to maximize their reimbursement. And improving cybersecurity is becoming more of a board issue, as companies have been exposed to huge data breaches and hacks. In fact, Michael W. Peregrine, with McDermott Will & Emery LLP, Chicago, told Bloomberg BNA, there is an ''expectation that the board will adopt formal cybersecurity oversight responsibilities.''

Pressure for oversight of cybersecurity issues is coming from yet another source, Reece Hirsch noted. ''The SEC has repeatedly emphasized in the past year that boards that fail to oversee and manage cyber risks do so at their peril,'' he said. ''As the health-care industry experiences an increasing number of significant breaches, this will be a critical corporate governance issues for health-care organizations in the coming year.''

Compliance Oversight. ''It's a new era for hospital boards, which need to be asking the right questions of management,'' Tom Mayo said. ''Hospital counsel have a vital role to play in prepping their boards for this increasingly critical function.''

Health-care provider boards are evolving, and in 2015, there was a ''notable shift by the larger nonprofit health systems to adopt governance practices more consistent in scope and responsibility with public companies of similar size and operational sophistication,'' Peregrine said. Particular emphasis has been placed on pursuing competency-based board selection; more precise executive succession practices; broader attention to director refreshment mechanisms such as tenure, term and age limitations and fitness-to-serve policies; assuring an equal distribution of labor across board committees; assuring a sufficient number of directors to address the increasing demands of the enterprise; and greater engagement between the board and the executive leadership team, he said.

Sandy Teplitzky said directors should read the HHS OIG's *Practical Guidance for Health Care Governing Boards on Compliance Oversight*. This guidance ''is intended to assist health-care providers understand the role, obligations and expectations of board members,'' he said.

The guidance isn't ''intended to set any particular standards or baseline,'' he said. ''Rather, it sets out the types of questions that board members should ask and provides suggestions as to what board members should do with the answers they receive.''

''Clearly, boards are responsible for setting the 'tone at the top' and ensuring that the organization has a comprehensive and credible compliance program,'' Teplitzky said.

Kim Roeder said health-care attorneys will be challenged in 2016 to assist directors ''in understanding the environment in which their organizations operate and their oversight responsibilities.'' The environment is extremely complex, and boards increasingly face multilevel regulation, shifting priorities and uncertainties in government funding, she said.

Individual Accountability. Directors and officers—and their attorneys—also need to be aware of an increased emphasis on individual accountability, board members said.

In 2015, there was a ''notable shift by the larger nonprofit health systems to adopt governance practices more consistent in scope and responsibility with public companies of similar size and operational sophistication.''

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

Peregrine pointed out that in one 2015 case, an appeals court upheld the assessment of $2.3 million in damages against a nursing home's officers and directors, who were accused of a breach of fiduciary duty that contributed to the deepening insolvency of the organization (*Official Comm. of Unsecured Creditors ex rel. Estate of Lemington Home for the Aged v. Baldwin*, 777 F.3d 620, 2015 BL 16998 (3d Cir. 2015)). He said the appeals court's analysis ''provides useful baseline references to board conduct that may violate the duty of care, trigger a punitive damages award and contribute to the organization's 'deepening insolvency.' ''

Sandy Teplitzky said that, although the Yates memo doesn't break new ground, it will have repercussions throughout 2016. It is ''an intensification of the DOJ's policy of threatening and indicting hospital and institutional board members and executives for alleged violations of the FCA, Stark Law and AKS,'' Katherine Benesch said.

Peregrine said the memo's most likely effect on providers ''may be on the organization's approach to legal compliance, its management of internal investigations, the provision of directors and officers insurance and indemnification, and board interaction with management on matters of regulatory concern.''

State-Level Issues. Gerry Griffith said he sees continuing attention on governance issues at the state level. State attorneys general and other regulators ''will continue to focus on conflicts of interest and insider deals'' as they review major transactions, he said.

Washlick agreed, saying community and state officials are calling boards to task ''with respect to how

   ISSN 1064-2137

they are exercising their fiduciary duty of care when exploring strategic partners and alternatives.''

7: QUALITY: Permeating All Facets of Health Law

One issue that touches all aspects of health law is a concern for quality of care. Almost every issue in this year's top ten—from hospital/physician alignment to fraud and abuse enforcement—includes at least some indication that the decision makers involved are concerned about maintaining and improving the quality of care that is available to patients.

John Blum told Bloomberg BNA that in the coming year ''increasing pressure will be felt to expand quality metrics to cover areas like patient engagement and social determinants of health that are hard to quantify.''

Tom Mayo agreed, saying that ''we've reached a tipping point where quality is sufficiently critical to enough aspects of health law that it has become as important to hospital boards as it is to patients and regulators.''

Medicare Payments. According to Vickie Brown, one of the primary goals of the ACA was to lower the costs of Medicare. She told Bloomberg BNA that the ''CMS anticipates that through a number of different initiatives, including the quality of care initiatives, Medicare costs will be lowered by as much as $260 billion through 2016.''

She also pointed out that the percentage of reimbursement to providers based on quality and value of service is expected to increase.

Brown said that ''this anticipated increase in 2016 is a clear indication that payers are becoming more serious about making quality and value a part of the reimbursement formula and will cause more consolidation of providers in the health-care market.''

Alternative Ventures. FTC officials have gone on record saying that one way to avoid consolidation in the health-care market and still be sensitive to the need to improve quality of care is by participating in alternative collaboration ventures, such as ACOs and population health initiatives.

According to Michael Schaff, ''ACOs will continue to struggle to combine cost savings and quality of care.'' The ability of these organizations to understand and utilize data that measures quality of care will remain essential if ACOs are to stay competitive in 2016, he said.

Gary Herschman agreed, saying that ''providing quality, cost-effective care is clearly the name of the game in the new, post-ACA health-care marketplace, and is imperative in connection with clinical integration efforts and succeeding in population health initiatives and risk-based ventures.''

Providers should spend 2016 focusing on strategies to implement the IOM report's recommendations for eliminating diagnostic errors.

ELISABETH BELMONT, MAINEHEALTH, PORTLAND, ME.

But Kim Roeder sounded a note of caution. She said that there are ''lots of quality metrics for providers to monitor, though the efficacy of those measures is unclear.''

She added that the ''mid-year report by the Medicare Payment Advisory Commission was interesting because it questioned whether the many quality metrics in use actually lead to better outcomes and lower costs.'' She noted that ''providers are devoting resources to meeting quality criteria, but the report raises a question as to whether that really promotes better outcomes.''

Diagnostic Errors. The Institute of Medicine (IOM) in 2015 released a report that focused on eliminating diagnostic errors, which the report claimed ''persist throughout all settings of care, involve common and rare diseases and continue to harm an unacceptable number of patients.''

Elisabeth Belmont told Bloomberg BNA that this report should be a particular point of emphasis for providers looking to increase the quality of care they offer.

Pointing out that diagnostic errors are ''a leading cause of malpractice claims, and these claims are more likely to be associated with patient deaths than other types of medical errors,'' Belmont said she believes that providers should spend 2016 focusing on strategies to implement the report's recommendations.

8: HEALTH PLAN REGULATION: Plans Face Challenges in 2016

Health plan regulation ranked high on many board member's lists of health law issues to watch in 2016. Changes in policy wrought by the ACA, and the survival of the Obama administration's pivotal health-reform initiative itself, will affect how health-care attorneys advise health plan clients in the coming year, they said.

''Health plans are facing enormous challenges,'' Kirk Nahra told Bloomberg BNA. These include data issues, cybersecurity risks and antitrust concerns, he said. They are also concerned with the continued viability of ACA-inspired business models, mounting regulatory obligations and cost challenges, Nahra said. ''Expect to see lots of change in the business environment for health plans over the next few years, with the need for government regulators to stay on top of these developments while not unduly impeding them.''

Howard Wall said that, in light of the government's win on the subsidy issue in *King v. Burwell*, 135 S. Ct. 2480, 2015 BL 202885 (U.S. 2015), ''there should be an expectation that the implementation of the ACA can proceed on a more reasonable timeline.'' However, he said, ''with the entire GOP presidential field vowing to repeal Obamacare and the new Congress led by Paul Ryan pressing forward with repeal votes, the battle to keep the gains in coverage achieved by the ACA will continue during 2016.''

Narrow Networks. Kim Roeder said that the issues with narrow networks—that is, plans that limit the number of in-network providers—are still around, and John Blum predicted that network adequacy will be an even bigger issue for plans as they struggle to balance access pressure with the need to control costs.

''It will be interesting to see, in different markets, which of these competing pressures prevails,'' Richard Raskin said.

''Just how narrow networks may be already is a critical issue and could be more so if all the pending insurer mergers are approved,'' Mark Waxman told Bloomberg

BNA. Waxman said the other main issue he sees arising in 2016 is whether plans will ''take the lead on quality improvement or simply try to drive costs down.''

Reece Hirsch foresees problems with HIPAA compliance growing out of health plan reform. ''State health exchanges are requesting large volumes of plan member data from participating health plans,'' he said. ''That information sharing can raise complex HIPAA compliance issues if it is not properly structured and limited.''

Jack Rovner said to expect ''further moves to consolidate, further co-op financial failures, further moves to narrow networks in benefit design and further moves to payer-provider collaboration of real 'partnerships' focused on the ultimate consumer, rather than the traditional zero-sum buyer-vendor arrangement.''

''Just how narrow networks may be already is a critical issue and could be more so if all the pending insurer mergers are approved.''

J. MARK WAXMAN, FOLEY & LARDNER, BOSTON

In the private health insurance market, Vickie Brown said, ''insurance premiums, deductibles and co-pays have been rising significantly, and employers are shifting more of the costs of health insurance to employees.'' She predicted the HHS's Department's Center for Consumer Information and Insurance Oversight ''will decide to play a more significant regulatory role'' in 2016 ''to address the issue of increased health insurance costs being shifted to employees.''

Mark Kadzielski said health plans will become targets of regulatory enforcement under the ACA's antidiscrimination regulations and the Mental Health Parity Act. State enforcement also increasingly will be a focus in 2016, he said.

Future of ACA? The coming year ''will be another year of political challenges to the ACA,'' Katherine Benesch told Bloomberg BNA, with Republicans still calling for its wholesale repeal. The House's legal challenge to cost-sharing payments made to insurers by the HHS (*U.S. House of Representatives v. Burwell*, D.D.C., No. 14-1967, *filed* 11/21/14), and the Supreme Court's second look at the contraceptive mandate (*Zubik v. Burwell*, U.S., No. 14-1418, *review granted* 11/6/15) ''must be watched,'' she said.

Nahra said he is amazed by ''how many legal challenges remain to key portions of Obamacare.'' This, he said, ''results in ongoing disruption of the reform program, nitpicking at the edges that reduce the effectiveness of the programs—making it less likely that the overall package will 'work'—and uncertainty and confusion with each major challenge.''

''The apparent failure of so many of the exchange co-ops and similar off-shoots is also creating a lot of new concern,'' Nahra said. ''All of this uncertainty and confusion is not good for any element of the health-care system.''

Lowell Brown predicted that discussions about the reform of the ACA will begin immediately after the November election, regardless of which party is in power.

Although several advisory board members suggested that Congress would be looking particularly at a repeal or revision of the ''Cadillac'' tax in 2016, that already has occurred, with a late-2015 vote to delay the tax's effective date.

Doug Ross told Bloomberg BNA that ''the war over the future of the ACA is far from over and likely will be decided by the marketplace and not in the courts.''

9: TELEMEDICINE: Driving Delivery Innovation

Telemedicine, or telehealth, is expected to play a larger role in the coming year, given the development of technologies to allow more remote access to health-care providers, as well as insurers' expansion of coverage for such services, advisory board members said.

According to Phil Zarone, technological changes, and the pace at which they are occurring, make it ''difficult for health-care providers to know how to apply existing law'' in the health-care field.

In addressing the growth of telemedicine, Vickie Brown predicted that developing technologies will be used, ''to increase access to and delivery of health care to more individuals at a lower cost,'' such as in a home-based setting.

''Telemedicine will continue to expand as a vehicle for the delivery of health-care services,'' Mark Kadzielski said. For consumers, it provides increased access to services, while incentives in the MACRA have provided health-care entities with reasons to adopt it, he said.

Legal Hurdles to Overcome. Kadzielski warned, however, that the ''legal issues surrounding telemedicine are many, and the pitfalls are significant.'' The failure to ''properly structure telemedicine agreements, including credentialing providers who are rendering actual services to patients, is a chronic problem that will only get worse,'' he said.

Additionally, the failure ''to properly secure health information transmitted and stored by providers, telemedicine entities and others in the chain of electrons will continue to create privacy risks.''

The ''explosion'' of telehealth and its increasing use as a means of improving access in rural areas and augmenting specialties makes it attractive to academic medical centers ''looking for new sources of revenue and non-U.S. specialty providers,'' Gerry Griffith said.

But, John Washlick said, ''many states and third-party payers haven't yet caught up with the technology that supports telemedicine.'' Implementing telemedicine in some states ''is a cumbersome endeavor and often involves negotiating draconian local laws pertaining to the corporate practice of medicine and fee splitting,'' he said.

State Licensing Concerns. The increased use of telemedicine also depends, to some extent, on state licensing requirements. Michael Schaff said that 11 states in 2015 adopted the Federation of State Medical Board's Interstate Medical Licensure Compact, and nine other states have introduced legislation to follow suit. This compact provides for an expedited licensure process for eligible physicians and is intended ''to improve license portability and increase patient access to care,'' he said. The compact ''may eliminate some of the barriers to practicing telemedicine across state lines.''

Vickie Brown predicted that flexibility in state licensure, created by tools like the multistate compact, ''will

   ISSN 1064-2137

place increased pressure on payers to focus on increased reimbursement for telemedicine.''

John Blum suggested that ''this may be the time for the law finally to catch up as there is an increased focus on these technologies in the face of access and competition pressures.''

Schaff also noted that professional liability issues concerning telemedicine will become important in 2016. ''Providers who engage in telehealth need to check their malpractice insurance coverage to determine whether it includes telemedicine/telehealth services,'' he said.

Flexibility in state licensure, created by tools like the multistate compact, ''will place increased pressure on payers to focus on increased reimbursement for telemedicine.''

VICKIE YATES BROWN, FROST BROWN TODD LLC, LOUISVILLE, KY.

Gary Herschman noted that mid-level practitioners also ''are playing a greater role in expanding access to care via these technologies.''

10: MEDICAID: Cost of Expansion and Managed Care Adoption

Medicaid will present two interrelated but distinct challenges for health lawyers in the coming year, according to advisory board members.

The first involves the expansion of the Medicaid program under the ACA, along with the extent to which it has affected the budgets of the states that chose to participate, even after considering the federal funds that are available to cover the costs until 2017.

The second involves agreements with managed care organizations, which states are entering to defray those costs.

Expansion Costly. According to John Blum, ''there are still some states in play on the expansion front but regardless of where a state stands, cost containment, oversight and coverage issues pose challenges.''

But, Vickie Brown said, those states that decided to expand their Medicaid programs under the ACA ''are finding that in spite of the fact that the federal government is covering the cost for the newly eligible individuals insured through Medicaid through 2017, they did not adequately anticipate or budget for the actual costs to implement Medicaid expansion.''

She said that she believes that the states whose budgets are overwhelmed by the costs will reconsider their decision to expand the program and that even more states will reconsider after 2017.

T.J. Sullivan said that CMS flexibility is the key to getting states to expand their Medicaid programs.

''CMS has shown more flexibility, and states like Montana have responded favorably, but it may be after the next election cycle before a significant number of holdout states come to the table,'' he said.

Howard Wall agreed, saying that, ''after the 2016 election, with President Obama out of office, the political lightening rod for conservatives will be removed and strong pressure from provider groups could lead more states in the direction of accepting expansion, especially if it can be packaged as a politically acceptable Medicaid reform program.''

Mark Kadzielski expressed hope that the election year politics might actually help expansion. ''The expansion of state Medicaid programs is the other shoe that will help fulfill the promise of the ACA,'' he said.

''In this election year, there is hope that more expanded coverage will be accomplished albeit for purely political reasons,'' he added.

Managed Care Regimes. Wall said that it is likely ''that the lame duck administration will continue to look favorably on granting waivers to implement Medicaid managed care and other initiatives as a way to achieve expansion and fulfill the aspirations of the ACA.''

With the increase in covered individuals caused by the Medicaid expansion that has already occurred under the ACA, ''the challenge of cost will continue to force a push to managed care,'' Mark Waxman said.

However, he pointed out that one major issue that has yet to be settled will be ''how that will play out in terms of whether there are an adequate number of practitioners to provide the necessary access, and whether states will pay for that access where there are shortages.''

Jack Rovner predicted that ''the growth of managed Medicaid will increase as an apparently financially- and care-management-attractive alternative for states and a significant business expansion opportunity for health insurers.''

''Managed Medicaid, whether through SSA Section 1115 waivers alone or in combination with ACA Section 1332 State Innovation Waivers, is likely to continue to be an attractive alternative to Republican state politicians who eschew ACA Medicaid expansion,'' he added.

HONORABLE MENTION: TAXATION

One issue that nearly cracked the top ten, and thus earned an honorable mention for this year's outlook was taxation, as board members identified challenges for nonprofit health-care providers on both state and federal fronts.

A property tax case from New Jersey left a number of board members questioning whether nonprofit providers will be able to maintain their tax-exempt status in the coming years. Although many states and localities recognize a real property tax exemption for charitable institutions, including nonprofit hospitals and health systems, a New Jersey tax court in June ordered a health system to pay back taxes on parts of its organization that were operated on a for-profit basis (*AHS Hosp. Corp. v. Town of Morristown*, 28 N.J. Tax 456, 2015 BL 206190 (N.J. Tax Ct. 2015). These included the hospital gift shop and other operations.

The parties settled their dispute in November. The hospital will pay over $15 million in back taxes and interest and approximately $1 million each year going forward.

Michael Schaff said the tax court's ruling could have ''a significant impact on the tax-exempt status of nonprofit hospitals across the country.'' He advised that providers in 2016 review their activities ''to determine whether their operations and structure allow the hospital's property to be used substantially for profit.''

Gary Herschman agreed that the tax court's ruling should prompt all nonprofits to conduct ''internal assessments of their activities under the standards set out by the court.'' They should implement ''changes as necessary to reduce their potential exposure in this area,'' he said.

Now that it has worked in New Jersey, there may be a ''renewed attack on hospital property tax exemptions'' elsewhere, due largely to state budgetary pressures, Gerry Griffith said.

The New Jersey decision ''reminds us that the IRS is not the only game in town,'' T.J. Sullivan said. ''In states like Pennsylvania, Illinois, Texas and now New Jersey, providers also have to pay close attention to how to satisfy state and local regulators with their charitable activities.''

The New Jersey decision "reminds us that the IRS is not the only game in town."

T.J. Sullivan, Drinker, Biddle & Reath LLP, Washington

Financial pressures on state and local governments may cause the issue to ''spread further, though stepped up public involvement in community health needs assessments and the increased transparency mandated by the ACA, along with compliance with federal tax requirements, may actually help tax-exempt hospitals avoid some local troubles,'' Sullivan said.

Federal Concerns. On the federal level, anecdotal evidence suggests that ''full compliance with Section 501(r) remains uneven, but the final regulations take effect shortly, and the IRS—cash-starved though it may be—has warned that 501(r) compliance will be a top examination priority'' Sullivan said.

Section 501(r), included in the ACA, requires nonprofit hospitals to annually assess community health needs, implement changes in their financial assistance and billing and collection policies, and undertake other initiatives to demonstrate their continued entitlement to federal tax exemption.

''Take this to heart: if your financial assistance policy is not complete, compliant and on your website by New Years, you might get a Valentine's Day visit from an IRS agent,'' Sullivan warned.

Tom Mayo added that complying with the increased 501(r) reporting requirements added by the ACA, along with making the operational changes needed to meet those requirements, ''will be a big concern'' in 2016.

Griffith predicted that the IRS ''will become more visible in health-care audits.'' The audits will include ''the first reviews of clinically integrated networks, ACOs and other new structures for provider collaborations along with the second wave of review of nonprofit hospitals' community benefit activities,'' Griffith said.

''The stakes in these examinations for providers will be larger than initially apparent, given the lack of clear guidance on many of these issues, leading to a risk of case-by-case variations in how the IRS interprets the relevant code sections and regulations,'' Griffith said.

Mark Waxman also pointed to the difficulties faced by charitable health-care providers in maintaining their tax-exempt status after the ACA resulted in much greater health insurance enrollment throughout the country. ''With the change to many more covered insureds, the question about what makes a charity a charity in health-care delivery will take more of a central seat,'' he said.

Waxman added that this difficulty may be ''augmented as the for-profit entrepreneurs look to bail out struggling charity systems through joint ventures, management agreements and the like.''

By Mary Anne Pazanowski and Matthew Loughran

To contact the reporters on this story: Mary Anne Pazanowski and Matthew Loughran in Washington.

To contact the editor responsible for this story: Peyton M. Sturges at psturges@bna.com

  HLR ISSN 1064-2137