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Outlook 2015

Hospital/Physician Alignment, Health IT Top List of Health Law Issues for 2015

Ripple effects from the continued implementation of the Affordable Care Act will dominate all aspects of the roughly $2.9 trillion health-care industry in 2015, but the pivotal role hospital/physician alignment plays in accomplishing the ACA's goals made it the top health law issue of the new year, according to the advisory board of *Bloomberg BNA's Health Law Reporter*.

''It is difficult, if not impossible to find any hospital, hospital system, group practice or individual physician who has not approached or been approached to join forces in some form of an aligned hospital/physican relationship,'' Fredric J. Entin, with Polsinelli Shughart PC, Chicago, said.

Health information and technology ranked as a close second for the most significant health law issue for 2015. Board members cited provider struggles to implement electronic health record systems, an expected hike in Health Insurance Portability and Accountability Act government enforcement, continued data privacy and security woes and the implications of big data as reasons the topic has risen steadily in *HLR's* Top 10 list over the years.

Fraud and abuse traditionally ranks high and 2015 is no exception, holding steady at No. 3. Fraud and abuse issues ''impact every healthcare provider, and the substantial uncertainties about the law, coupled with the large potential liabilities, create a compliance minefield,'' Kim H. Roeder, with King & Spalding LLP, Atlanta, said.

Impact of ACA: 'Hard to Overestimate.' The ACA ''involves so many facets of health care delivery that it is hard to overestimate'' its impact, J. Mark Waxman, with Foley & Lardner, Boston, said, voicing the sentiments of many board members who ranked health plan regulation—and the U.S. Supreme Court's upcoming review of the ACA—as the fourth issue of the new year.

In 2015 the U.S. Supreme Court will decide whether Americans who buy insurance through exchanges in three dozen states may continue to get subsidies to help pay premiums (*King v. Burwell*, U.S., No. 14-114, *oral arg. scheduled* 3/4/15).

The case has the potential to strike a crippling blow to the ACA, and many board members noted that an administration loss, coupled with the Republican takeover of the Senate, could have dire consequences for the law.

While a wholesale repeal of the ACA is unlikely, Katherine Benesch said that ''what happens in the coming year in Congress and the Supreme Court will determine whether the whole system will be thrown into chaos or not.'' She is with Benesch & Associates LLC, Princeton, N.J.

Medicaid ranked fifth and Medicare came in sixth. Both massive programs continue to be shaped by ACA mandates, and the outsized role they play in the health-care industry make them perennial Top 10 favorites. Medicaid spending grew to $449.4 billion and Medicare climbed to $585.7 billion in 2013, according to the Centers for Medicare & Medicaid Services.

Health Law Reporter's Top 10 for 2015

1. The ripple effects associated with **hospital/physician alignment** pressures make this the top issue.
2. **Health information and technology** poses privacy and data breach risks while exerting cost and adaptation challenges.
3. Compliance challenges and liability risks of **fraud and abuse** enforcement demand continued attention of provider counsel.
4. **Health plan regulation** is a major concern as the U.S. Supreme Court considers health insurance subsidies under the ACA.
5. The impact **Medicaid** program expansion has on state budgets, providers and recipients should become more clear.
6. **Medicare** audits and changing reimbursement rules challenge providers' ability to maintain revenues.
7. Pressure to obtain and document **health-care quality** improvements continues to mount.
8. **Antitrust** issues continue to confound practitioners seeking to pursue the ACA's collaborative care goals.
9. Provider organizations must improve **corporate governance** effectiveness to avoid substantial liability exposure.
10. **Licensure** concerns mount as health care moves to more fully embrace telemedicine.

Quality of care, which is both a goal and a measurement of success under the ACA, was seventh. Michael F. Schaff, with Wilentz, Goldman & Spitzer PA, Woodbridge, N.J., said that the ''ability to understand and utilize data which measures quality of care will be essential'' to providers who want to stay competitive in 2015.

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Rounding out the Top 10 were antitrust (eighth), corporate governance (ninth), and licensure (10th). Board members ranked medical staff issues, taxation and labor and employment as honorable mentions.

1. Hospital/Physician Alignment

The continued imperative for greater alignment of hospitals and physicians to meet the quality-improvement and cost-saving goals of the ACA propelled the issue to No. 1 on *HLR's* Top 10 list for 2015. The issue has advisory board members' attention, they said, because changes in affiliation have a discernible ripple effect with respect to antitrust, fraud and abuse, quality, payment and most other practice areas.

The number of arrangements designed to enhance coordination among providers, all of whom are endeavoring to respond to the pressures of accountable care organizations, quality metrics, care improvement, HIT adoption and other clinical integration initiatives, will continue to rise, they said.

''Although the many forms in which alignment can be achieved between and among providers who previously just coexisted continue to evolve, this is not just another fad that the reluctant or skeptical can ride out,'' Fred Entin said.

The trend in provider consolidation and ACO-type alliances will accelerate in 2015, with these forms of physician-hospital alignments being touted as the path to achieving the ''triple aim'' of better quality, lower cost and better population health, Jack A. Rovner, with The Health Law Consultancy, Chicago, said.

Gerald M. Griffith, with Jones Day, Chicago, agreed. ''Changes in payment models and increased cost and complexity of operating a private practice will continue to lead more physicians to employment models and other intermediate steps that increase their ties to hospitals and larger health plans,'' he said.

The alignment of hospitals and physicians is a logical outgrowth of health-care reform objectives. ''A significant objective of the integration strategy is building an accountable care infrastructure of primary care physicians and specialists to be positioned to succeed in the new value-based reimbursement and population health management environment,'' John R. Washlick, with Buchanan Ingersoll & Rooney, Philadelphia, said.

Employed Physicians, Concerns Abound. The relationship between hospitals and physicians—particularly the increasing employment of physicians—is extremely important because it directly affects how care is provided, Phil Zarone, with Horty Springer & Mattern PC, Pittsburgh, said. At the same time, however, it creates uncertainty for health-care attorneys because employed physicians are subject to both the medical staff bylaws and their employment agreements and because there is little in the way of judicial guidance on how to sort out disputes that inevitably arise.

Although increased employment of physicians by hospitals may solve some problems, it creates many others. Mark A. Kadzielski, with Pepper Hamilton LLP, Los Angeles, noted the tension between employment decisions and decisions involving credentialing and medical staff privileges.

''For example, does HR deal with disruptive physicians like all other employees, or are they dealt with by the medical staff?'' Kadzielski asked.

Other compliance issues lurk as well. ''Many of these arrangements will push the compliance envelope of Stark, the Anti-Kickback Statute and exempt tax rules,'' Entin said. ''In addition, as more providers affiliate and align, those that have not will have fewer opportunities to have a meaningful role in newly configured delivery systems.''

Katherine Benesch cited the tension between the move to greater alignment between hospitals and physicians and efforts by ACOs and insurance carriers to develop ''narrow networks'' that try to limit the number of providers who gain entry into the network, in order to control cost and quality.

Dawn R. Crumel, Shipman & Goodwin LLP, Washington, said that ''hospitals and physicians alike need to determine if there is a cultural fit and what the physician practice will look like after integration.'' Although physician employment after a practice acquisition needs to be carefully balanced to encourage integration, it is also important to ensure that whatever made the physician productive before the acquisition stays in place, she added.

Lowell C. Brown, Arent Fox, Los Angeles, suggested the alignment pressures pose a challenge for providers in states such as Texas and California that prohibit the corporate practice of medicine.

Hospital/physician alignment "is not just another fad that the reluctant or skeptical can ride out."

—Fredric J. Entin,
Polsinelli Shughart PC, Chicago

''Every hospital is looking for ways to team up with physicians but in corporate practice of medicine states, this will be a major challenge, and may result in pressure for legislation,'' he said. ''Organized medicine will fight back hard if that occurs.''

Michael Schaff said health lawyers in 2015 should apply the lessons learned from past hospital/physician alignment initiatives in structuring new arrangements. ''It will be very important to follow the evolution of alignment strategies and then learn from the growing pains encountered by alignments implemented in 2012, 2013 and 2014,'' he said.

2. Health Information and Technology

Technological innovation, stepped up enforcement, privacy and security risks, data analytics, and provider struggles with the adoption of electronic health record (EHR) systems are just some of the reasons board members ranked health information and technology second on the Top 10 list for 2015.

''This is a dynamic area with regard to enforcement risk, operational issues, and evolving regulatory standards and information technology,'' Robert L. Roth, Hooper, Lundy & Bookman PC, Washington, said. Connectivity and interoperability are desired by many in the health-care industry, but concerns about cost and privacy abound, he said.

Buzz Word: Interoperability. Interoperability is the ''buzz word'' these days, said Dawn Crumel. The technical standards are there, but ''more uniform clinical standards for the data'' are needed. Vendor-based systems may not be matching up, she said, even among

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providers who use the same vendor. EHR systems need to become ''consumer driven.''

Progress toward interoperability has been ''painfully slow,'' according to T.J. Sullivan, with Drinker Biddle & Reath LLP, Washington, due partially to the cost of preferred EHR technology. It is a ''significant consideration when evaluating potential alignment strategies,'' he said.

John Washlick agreed with Sullivan on the importance of technology to clinical integration. Sophisticated technology infrastructures that connect providers to hospitals and payers are needed, not only for interoperability purposes, but also as a tool to measure the use of evidence-based protocols that are ''critical to the success'' of these entities, he said.

Elisabeth Belmont, with MaineHealth, Portland, Maine, broke this very broad topic into subsets that show just how many questions health-law practitioners will have to deal with in the coming year, including telemedicine and remote patient monitoring, big data, data governance, embedded and wearable technology, carehacking, EHR audits, patient safety and privacy breaches.

Carehacking is a relatively new concept, Belmont said. The term describes patients' use of social networks, forums, websites and other digital information sources to augment the information they receive from health-care providers. These information sources may help patients ''understand and make more informed decisions regarding their medical care.''

Providers' inability to review patient-generated data and determine what may be relevant to diagnosis or treatment may increase their liability exposure, Belmont said.

Privacy, Unregulated Health Data, Big Data. Big data is fast becoming ''the new normal,'' Belmont said. Providers' compliance efforts should focus on how the use of these data is changing the compliance landscape and the risks of using it.

Belmont also cited the increasing use of embedded and wearable technology, which allows consumers to measure and enter their own health-care data into their EHRs. Health-care providers need to review policies to determine whether they will allow the use of these technologies by employees and patients and how they will use the information generated, she said.

There are still ''way too many security breaches in the health care area.''

KIRK J. NAHRA, WILEY REIN LLP, WASHINGTON

Overall, privacy and security are hot areas in the health industry these days, according to board members. There are still ''way too many security breaches in the health care area,'' Kirk J. Nahra, with Wiley Rein LLP, Washington, said. Health-care companies ''need to do a better job'' of protecting vital records. The big development to watch for, however, concerns data that are largely unregulated, he said.

''Any company that gathers, uses or discloses any information that is reasonably considered health information or information that might be useful to entities in the health care industry needs to pay attention to this issue and figure out their role in the public debate (as well as how this debate will affect their business),'' Nahra said.

Mark Kadzielski predicted that data breaches will become ''more prevalent,'' despite the imposition of ''record fines'' on both the federal and state levels in the past year. ''Providers need to employ an entire arsenal of experts for breach avoidance as well as post-breach guidance,'' he advised.

Reece Hirsch, with Morgan, Lewis & Bockius LLP, San Francisco, agreed. Recent large breaches suggest ''that health care organizations need to harden their security against sophisticated hacks and cybercriminals.'' The ''threat of breaches now extends far beyond employee mishandling of medical information,'' he said.

Expect More Enforcement. Several board members, including Washlick, Kim Roeder and Michael Schaff, predicted that the Health and Human Services's Office for Civil Rights (OCR) will bring more enforcement actions in 2015 and that the health-care industry could find itself subject to greater fines, as well as civil litigation.

Howard T. Wall III, with RegionalCare Hospital Partners Inc., Brentwood, Tenn., said he expects ''efforts to improve compliance programs and audit functions will intensify'' in light of OCR's stepped up enforcement activities. These activities include the commencement of Phase 2 HIPAA audits in 2015.

''Covered entities that can't produce current compliant HIPAA policies, procedures and documentation may face enforcement action,'' Hirsch said. Gary W. Herschman, with Sills Cummis & Gross PC, Newark, N.J., added that covered entities and business associates need to be ready to respond rapidly to OCR actions. Entities subject to ''desk audits'' will have ''only two weeks to provide OCR with all documentation, and may not have an opportunity to provide additional information thereafter,'' he said.

3. Fraud and Abuse

A perfect storm of health reform payment innovations, provider alignment changes, huge amounts of Medicare and Medicaid money, exceedingly complex regulatory requirements and increasingly sophisticated government and private enforcement converged to make fraud and abuse a top health law issue for 2015, according to advisory board members.

''More than anything else, this is what keeps health-care lawyers and compliance officers up at night,'' Lowell Brown said of fraud and abuse.

''The complexities and ambiguities in health care regulation continue to grow, almost geometrically, virtually ensuring providers and plans will have occasional stumbles,'' Gerry Griffith said.

According to the Justice Department, False Claims Act litigation alone recovered $2.3 billion from the health-care industry in fiscal year 2014, down from $2.7 billion in fiscal year 2013.

Fraud and abuse considerations ''surround every transaction,'' T.J. Sullivan said.

The adoption by health-care providers of new organizational relationships is making a difficult situation even worse, Phil Zarone said. ''The very innovations that reflect the changing demands of the public and the government are continually frustrated by incredibly complex and vague fraud and abuse laws,'' he said.

Aggressive contracting, business venture formations and other arrangements between hospitals and physicians in an effort to form new competitive delivery systems will invite more scrutiny and enforcement, Fred Entin said.

''The desire to beat the competition to an affiliation with a necessary component of an integrated organization could lead to concessions to beat the competition that are unlawful,'' Entin said, and ''the government is having too much success to lessen the pressure.''

''Recent court decisions indicate that juries and judges may interpret the law in a way at odds with what the informed members of the health law bar may have thought,'' Mark Waxman said.

No Enforcement Let-Up. According to Richard Raskin, with Sidley Austin LLP, Chicago, the Justice Department has a well-stocked pipeline of pending investigations and cases involving health-care providers and drug and device manufacturers, and the relators' bar is willing to litigate FCA cases regardless of whether the DOJ intervenes. He pointed to the potential for administrative sanctions; private litigation premised on alleged anti-kickback statute (AKS), Stark, or billing violations; and state FCA cases premised on violations of Medicaid or other state health law requirements.

''All in all, a huge area of exposure, with strong incentives for government, whistleblowers, and sometimes even competitors to aim for big recoveries, and for providers and manufacturers to establish strong compliance mechanisms to help ward off exposure,'' Raskin said.

Bob Roth said fraud and abuse enforcement, particularly under the FCA, will continue to be a compliance headache because of the cost, disruption, ''utter randomness,'' adverse publicity, and high risk posed by whistle-blower actions, as opposed to government enforcement actions, which tend to be more deliberate and less random.

''While providers can effectively plan for routine F&A issues, there is not much that providers can do to prepare for a whistle-blower case, except to have an effective compliance plan and hope that the 'fickle finger of FCA fate' points elsewhere,'' Roth said.

Elisabeth Belmont said she also expects continued robust enforcement and pointed to the HHS OIG Fiscal Year 2015 Work Plan as enunciating a range of target areas about which providers should be aware.

''With 28 states expanding Medicaid pursuant to the ACA, I expect fraud and abuse efforts to be intensified in 2015 as the government will need to provide more coverage and services with insufficient funding,'' Vickie Yates Brown, with Frost Brown Todd LLC, Louisville, Ky., said.

And, as if the threat of civil exposure weren't enough, government enforcers have signaled that FCA cases could lead to criminal investigations and prosecutions, Reece Hirsch said.

Look Out for Developments. The focus of recent cases on fair market value compensation and bonus arrangements for employed physicians—including bonus arrangements computed on personal work effort of the physicians—indicates that even relatively safe employment arrangements aren't immune from challenge and can give rise to significant liability, Kim Roeder said.

Sanford V. Teplitzky, with Ober Kaler, Baltimore, said he expects continued fraud and abuse developments with respect to physician employment agreements—concerning the validity of the employment relationship or the fair market value of the compensation paid to the employed physicians—and the issue of whether Stark applies to Medicaid.

Roeder also pointed to the published outcomes of matters settled through the CMS Self-Referral Disclosure Protocol and said they have been encouraging to the provider community. ''However, there continues to be a significant lag in resolution of matters disclosed through this protocol, perhaps due to the inherent complexity of these matters and the volume of disclosures,'' she said.

The fate of pending legislation to streamline the settlement process for ''technical'' violations will be a point to watch in 2015.

''With 28 states expanding Medicaid pursuant to the ACA, I expect fraud and abuse efforts to be intensified in 2015.''

—Vickie Yates Brown, Frost Brown Todd LLC, Louisville, Ky.

Teplitzky agreed, noting that members of Congress also apparently are considering possible legislative action that would establish a flat fee payment for technical or procedural noncompliance situations.

Teplitzky also pointed to developments with respect to corporate integrity agreements, where the OIG continues to signal its intent to fashion CIAs that more closely reflect the OIG's view of the seriousness of the activity leading to the CIA. He cited the appointment of a five-year monitor in a recent settlement as evidence that the OIG may require more intensive oversight as a condition of waiving its exclusion authority.

4. Health Plan Regulation

The U.S. Supreme Court's decision to review *King v. Burwell* in 2015—a case likely to determine the viability of the Affordable Care Act's health insurance exchange program and, possibly, the law itself—is a prime reason board members placed the issue fourth on the list for 2015.

Douglas Ross, with Davis Wright Tremaine, Seattle, Jack Rovner, Kim Roeder, T.J. Sullivan, Bob Roth and Thomas Wm. Mayo, with SMU/Dedman School of Law, Dallas, specifically cited *King* as a decision to watch in 2015, with Mayo saying it will have ''huge implications for the future of the ACA.''

In it, the court will decide whether individuals who buy health insurance on federally facilitated exchanges, which exist in the majority of states, may qualify for tax credits or subsidies. According to a Dec. 30, 2014, HHS report, about 87 percent of people who selected health insurance plans through federally facilitated exchanges as of Dec. 15, for coverage beginning Jan. 1, were deemed eligible for subsidies, compared to 80 percent of enrollees who selected plans over a similar period in 2014.

Challengers to the rule argued that the ACA allows only state-run exchange purchasers access to subsidies or tax credits.

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The outcome of the case could determine whether the ACA sinks or swims, and the fate of the law will have ripple effects throughout the health-care system. If only state-run exchange buyers are eligible for subsidies, there is less incentive for individuals to buy insurance on federally facilitated exchanges. It is believed that only people who really need health-care coverage, including the elderly and individuals with chronic conditions, will subscribe. Absent participation by the so-called young invincibles, the risk sharing that is key to the ACA won't be there, and the entire program will fall into a death spiral.

Thus, a successful challenge to the Internal Revenue Service rule that makes subsidies available to purchasers on federally facilitated exchanges as well as state-run exchanges would ''dismantle a key provision of the ACA'' and severely cripple the law, according to Vickie Brown. She added that a ''Republican controlled Congress will not likely attempt to repair the damage.''

Roth said that ''an adverse decision on the ACA subsidies could be very disruptive to continuing the trend of reducing uncompensated care.'' Richard Raskin said the case has ''the potential for major legal, political and policy consequences.'' A ruling that subsidies are available only to purchasers on state-run exchanges ''has the potential to significantly undercut the program,'' he added.

The exchange program has promoted ''an explosion of creativity with respect to plan design, including the recent 'skinny' plans,'' Roth said. This could be ''derailed,'' depending on the court's decision in *King*, he said, but he predicted that the ''burst of innovation'' will continue.

Raskin added that insurers' adoption of narrow networks to meet ACA requirements while keeping costs down may draw regulatory scrutiny. Narrow networks also may be the subject of litigation, as providers removed from or denied inclusion in health plan networks fight insurers' decisions, Mark Kadzielski said. In any case, consumers' negative reactions to such plans will ''put this issue in the spotlight,'' Roeder said. Lowell Brown predicted that state legislatures ''will feel pressure to intervene.''

The biggest question in health plan regulation is the future of the ACA as a whole. ''The implementation of the ACA is the central driver in the health care sector and thus the most significant driver in health law developments,'' Howard Wall said. It is ''impacting traditional health plan issues'' and having a trickle-down effect on other significant health law issues.

The Republican takeover of Congress had many board members wondering if the ACA will survive. It is an ''evolving issue,'' according to Mark Waxman. Still, several board members said they believe a wholesale repeal isn't in the cards. Wall, for example, doubted that Congress would vote to repeal provisions prohibiting denials of coverage based on pre-existing conditions.

Katherine Benesch added that the exchanges so far have enrolled millions of individuals and families. This,

Honorable Mention: Medical Staff.

The tension between existing hospital rules governing medical staff membership and the move by a growing number of hospitals toward employing physicians make medical staff another important management and compliance issue for hospitals, advisory board members said. The phenomenon involving a health system's adoption of a unified and integrated medical staff covering multiple hospitals also is expected to play out in the coming year.

It is impossible to know whether the traditional independent medical staff model can survive in a coordinated accountable care environment, Howard Wall said, but moves by hospitals to require mandatory safety training, compliance with practice guidelines and evidence-based best practices and HIT utilization through medical staff bylaws may be a sign of things to come.

''Fights over mandatory call will be last year's news as the medical staff of the future will demand more of its members or face the prospect of becoming irrelevant as more and more practitioners become employees,'' he said.

Phil Zarone agreed. ''Hospitals will continue to struggle to determine how to relate to physicians who are both employed and members of the medical staff,'' he said.

Lowell Brown said all the issues dominating the Top 10 will affect medical staffs. ''For example, hospitals aligning with physicians will see many of their medical staff members becoming restive about perceived favoritism of physicians who are part of the aligned group,'' he said. ''In many cases, there will be political responses from those medical staffs.''

Vickie Brown said it is her impression that fair hearing provisions of medical staff bylaws may be going the way of the dinosaur. ''As hospitals continue the trend in 2015 to take on more physicians as employees, I predict that the importance of the fair hearing protections contained in the hospital medical staff bylaws to protect aggrieved physicians will continue to erode.''

Mark Kadzielski said there will be more pressure on medical staffs to do the hard job of measurably improving quality in hospital settings. He asked whether traditional peer review still is viable as a method for dealing with marginally performing physicians.

Elisabeth Belmont pointed to the clarification of CMS's Conditions of Participation that allows a multihospital system to utilize a unified, integrated medical staff structure rather than having a separate medical staff at each component hospital. ''A unified medical staff model could improve the efficiency and effectiveness of a health system's peer review processes, call coverage capabilities, quality improvement initiatives and emergency preparedness plans,'' she noted.

Michael Schaff agreed. ''It will be interesting to see the practical effect in 2015 of these unified medical staffs,'' he said.

in turn, ''bolstered hospitals that were teetering under the weight of legal requirements to serve patients'' who couldn't pay.

5. Medicaid

The ongoing experiment with Medicaid expansion under the ACA, and associated unknowns, makes it an important health law issue because expansion provides funding that enhances patient access to care, addresses the needs of many uninsured patients in states that have expanded coverage and poses financial hardships for patients and providers in states that refused to loosen program eligibility requirements, advisory board members said.

Although debate on this issue will be politically charged and further expansion appears unlikely, the benefits of expanding eligibility criteria could manifest themselves in the coming year, they added.

Medicaid expansion ''is turning out to be the most significant access enhancement resulting from the ACA and states have a critically important opportunity to use program expansion to improve the health of their populations and to manage costs,'' Douglas A. Hastings, with Epstein Becker Green PC, Washington, said.

Newly eligible populations will present major challenges for expansion states as it is uncertain whether managed care strategies will be any more successful now than they have been in the past, John Blum, with Loyola University Chicago Institute for Health Law, suggested. ''For states that haven't expanded, the pressures of traditional Medicaid will only continue with growth in elderly populations and in numbers of disabled individuals,'' he said.

Slow Pay, Low Pay. Provider reimbursement will continue to be problematic in 2015, Gerry Griffith said. ''As long as states are struggling financially, slow pay and low pay for Medicaid will make headlines.''

Lowell Brown said that, with Medicaid expansion, this issue no longer can be a secondary concern for providers. ''Medi-Cal pays less than half the cost of keeping a patient in the hospital for a day—and that is before the first aspirin is given—so CEOs are looking hard at Medicaid as a revenue source and wondering how it will impact their bottom lines,'' he said.

''The unfortunate alternative in states that have not expanded Medicaid is a crushing uncompensated care load for hospitals,'' T.J. Sullivan said. Because investor-owned and nonprofit hospital systems have done well in states where eligibility has been expanded, expect both interests to press their views on recalcitrant governors and legislatures in the remaining states, he said.

Kim Roeder noted that Medicaid compliance presents a real challenge for multi-state and national health-care providers to conform compliance efforts to the particular requirements of each state's law, rules and special programs.

Bob Roth predicted that, with the expansion of the Medicaid population and increased oversight and enforcement, Medicaid will be in the news often in 2015, including continued coverage of the politics of whether or not and how a state will engage the Medicaid expansion.

''Additionally, as CMS moves further along with its dual-eligibles program—for those covered by both Medicare and Medicaid—providers must continue to be wary about whether these otherwise Medicare patients are being used by the states to fill budget gaps rather than design programs that truly meet the special needs of this patient population,'' Roth said.

Politics, Budget Realities. ''The Republican sweep in the states in the fall 2014 elections bodes ill for Medicaid expansion, despite the empirical evidence that expansion significantly reduces a state's uninsured population and the cost of 'uncompensated' care,'' Jack Rovner said.

2015 could be the year that voters in states that declined to expand Medicaid realize that their federal tax dollars are going to other states to pay for their Medicaid expansion, he said. ''The ways in which ACA political opposition defies economic logic are legion.''

Tom Mayo agreed. ''The states that did not sign onto Medicaid expansion will probably be looking hard at that decision and its impact on their budgets,'' he said.

Vickie Brown pointed to the experience Kentucky has had in being one of the early adopters.

''As long as states are struggling financially, slow pay and low pay for Medicaid will make headlines.''

—Gerald M. Griffith, Jones Day, Chicago

''Kentucky had a greater number of enrollees than expected, so, even though the federal government will be assuming 100 percent of the cost of coverage of the newly eligibles for three years, there are now concerns by some that the state did not adequately quantify the financial impact caused by this cost shift to the states,'' she said. This issue and the financial impact of a growing deficit due to Medicaid will be closely monitored in the upcoming legislative session, she predicted.

6. Medicare

Ongoing problems with the Medicare recovery audit contractor (RAC) program, mandatory reductions in doctors' payments and experiments with new ACA-driven reimbursement models will demand the attention of health-care attorneys in 2015, securing Medicare's perennial place as a Top 10 health law issue.

The most important factor keeping Medicare on the list year after year, however, is its status as ''the largest payer for most full services hospitals and an important payer for many physician practices,'' Gerry Griffith said.

''With that much money on the line, it is guaranteed to make headlines,'' he said.

Medicare also plays an outsized role because it is a driver of how care is delivered, specifically whether a patient is admitted to the hospital or treated on an outpatient basis, Phil Zarone said.

Changes in the way Medicare reimburses providers for their services are expected to garner significant attention in the new year, Doug Hastings said. For a time, hospitals and health systems will be required to balance ''being paid a mixture of fee-for-service and value-based payments,'' he said.

Other ACA-driven changes, including how disproportionate share hospital (DSH) payments will be calcu-

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lated, as well as modifications to the wage index and geographical classifications, should be watched in 2015, Bob Roth said.

Several of the most interesting changes involve provider consolidation and how treatment by multiple providers will be reimbursed, Gary Herschman said.

Griffith cited the Medicare Shared Savings Program Accountable Care Organization (MSSP ACO) and ''various demonstration projects aimed at refocusing the payment system on quality rather than quantity'' as important health industry developments in the new year.

Hastings said he doesn't believe the shared savings model is sustainable. Instead, a ''carefully executed shift'' by providers ''to providing high value health care, which by definition includes lower costs and incentives to keep patients healthy,'' will be a better model for long-term success, he said.

Several advisory board members discussed particular issues they think will generate concern for attorneys in 2015. Michael Schaff and Kim Roeder said the CMS will have to deal with the backlog of RAC audits. Over 300,000 Medicare RAC appeals are pending, Schaff said.

Implementation of the two-midnight rule is ongoing and additional guidance regarding gainsharing programs is possible, Roeder added.

Katherine Benesch said the CMS will continue to evaluate new current procedural technology (CPT) codes, as well as site-neutral reimbursement levels. She also said the CMS will consider phasing out bundled and global payments for certain services.

Several board members, including Roeder, Benesch, and T.J. Sullivan, cited the mandatory cuts in physician reimbursement payments, due April 1, as an important issue for 2015. And, although a ''doc fix'' is possible, there is ''no easy solution in sight,'' Sullivan said.

In 2015, the Medicare bar will be closely watching ''provider challenges to various jurisdictional dismissals issued by the Provider Reimbursement Review Board and the resulting limitations on the ability of providers to seek judicial review of their reimbursement disputes,'' Bob Roth said.

And, as with every other issue in the Top 10, much depends on what Congress will do in 2015. ''With a new Republican Congress, Medicare cuts may be back on the table,'' Richard Raskin said.

7. Quality

Quality of care's emergence as a driver of reimbursement and enforcement propelled it to seventh on the Top 10 list for 2015. ''Improving the quality of patient care has become a key concern for providers because reimbursement now hinges on whether high quality care has been provided,'' Gary Herschman said.

Enforcement actions are ''increasingly'' being based on quality, Lowell Brown noted, while Phil Zarone said that False Claims Act lawsuits for medically unnecessary services also implicate quality issues.

Still, quality ''remains an elusive achievement,'' Jack Rovner said.

For one thing, quality care measurement is ''heavily dependent'' on technological advancements, John Washlick noted. For another, defining what constitutes quality of care is difficult.

Practitioners ''will need to define quality criteria in a way that is meaningful on a continuing basis,'' Kim Roeder said.

The good news is that there are new tools for measuring quality. ''Matrices to measure quality of care are coming of age,'' Katherine Benesch said.

The CMS in 2014 introduced the Qualified Clinical Data Registry, Vickie Brown noted. Along with the registry, eligible health-care providers can use a physician quality reporting system (PQRS) to enter data, including value-based payment (VBP) modifier data. The agency has been using incentive payments to encourage providers to report specific quality measures, which it then uses to determine how well providers are meeting certain quality metrics, she said.

In 2015, the agency will begin using the PQRS data to implement downward payment adjustments. Brown said she doesn't ''think most providers are prepared for this next phase.'' Howard Wall said that, with the introduction of the VBP penalties, ''providers who are unwilling to keep up will see fewer dollars and will face scrutiny from better informed patients.''

Achieving and maintaining high quality of care also is of concern for clinically integrated delivery systems, since their reimbursements depend upon the performance of each member, according to Fred Entin and Doug Hastings. The ACO model of sharing both benefit and risk highlights a potential setback to using quality as a basis for reimbursement for these entities, but CMS, in its upcoming ACO regulations, may include ''changes that make risk sharing more palatable to providers,'' Hastings said.

The ''ability to understand and utilize data which measures quality of care will be essential'' to providers who want to stay competitive in 2015.

—Michael F. Schaff, Wilentz, Goldman & Spitzer PA, Woodbridge, N.J.

''Adherence to evidence based protocols of care will increasingly be found in'' physician agreements within these new delivery models, Entin said. He predicted that there may be litigation if physicians find their income decreasing as a result of their failure to meet quality measurements set out in their contracts with ACOs and other integrated entities.

Elisabeth Belmont said that care models ''that emphasize care coordination across hospitals and health systems, other providers, and the community are a critical element for quality improvement.''

8. Antitrust

Continued consolidations in many health-care industry sectors seem all but inevitable in 2015, making antitrust enforcement, already hot in 2014, likely to intensify in the new year.

Both horizontal and vertical collaborations designed to improve care and manage costs are likely, and the number and array of collaborative structures—beyond ACOs and traditional mergers—are sure to attract the attention of government regulators and could spur actions by excluded competitors.

''Pressure for provider consolidation, including hospital acquisition of physician practices, will meet up against growing empirical data that consolidation in-

creases prices for health-care consumers without increasing quality or providing other value,'' Jack Rovner said.

Key court cases, such as *FTC v. St. Luke's* in the Ninth Circuit, are likely to be decided in 2015, ''which will provide significant direction concerning whether the 'ACA makes us do it' defense can trump federal competition law,'' he said.

Increased consolidation among hospitals and hospital systems, including hospital systems merging into mega-hospital systems, as well as acquisitions and mergers to form larger physician groups will lead to increased antitrust scrutiny and enforcement initiatives, Gary Herschman said.

''Antitrust issues also will continue to be a major focus as ACOs continue to grow and more clinically integrated networks are formed to pursue population management contracts with commercial payers,'' he said.

Katherine Benesch cited the federal government's emphasis on hospital/physician alignments—including ACOs—as well as a growing number of institutional and system mergers in health care, as forces that are once again pushing the antitrust laws to the forefront.

While antitrust lawsuits by the government and private parties left out of consolidations are on the rise, the use by payers of ''narrow networks'' to limit the number of physician and hospital providers will likely increase the frequency that restraint of trade allegations are leveled, she said.

'Urge to Merge' = FTC Scrutiny. Richard Raskin predicted that consolidation among health-care providers will continue to draw close scrutiny from the Federal Trade Commission and, in some cases, state antitrust officials.

''Expect to see new government challenges as well as private suits directed at mergers, joint ventures, and network arrangements such as ACOs,'' he said. ''In the pharmaceutical sector, there will be continuing close examination of pharmaceutical patent settlements and drug company mergers, with a need for careful counseling on potentially exclusionary practices such as bundling, tying, and exclusive contracting.''

M&A transactions are still on the rise, John Washlick said, and with an unending ''urge to merge,'' some hospitals and health systems are combining to form ''alliances'' or ''networks'' without actually merging or transferring assets.

''Many of these alliances or networks have sprung up in reaction to mergers and acquisitions that are perceived to threaten their service markets,'' Washlick said. ''As a result of the surge of M&A and other strategic affiliations, antitrust is a serious consideration for determining whether these transactions can occur in the first place and how much the parties can do without violating antitrust laws.''

Tom Mayo said that at least one knowledgeable health system CEO has predicted that all private hospital care in the U.S. will eventually be provided by 50 systems.

Honorable Mention: Taxation.

As the IRS regains momentum after reorganizing and tax-exempt providers struggle to implement billing and collection, community health needs assessment and financial assistance requirements imposed on charitable hospitals under Section 501(r) of the Affordable Care Act, taxation will continue to command significant attention from health-care attorneys in 2015, according to advisory board members. Developments at the state level also could be significant, several said.

T.J. Sullivan said that, as the IRS struggles with its Section 501(c)(4) political activity challenges and its internal reorganization, things actually may get better for those seeking recognition of exemption or private letter rulings.

''However, it's hard to imagine the IRS putting much of its scarce resources into new initiatives beyond those required to fully implement the ACA,'' Sullivan said. ''In addition, providers and their counsel will continue to struggle with applying existing guidance to joint ventures and other affiliation arrangements between nonprofit and for-profit providers.''

The IRS will be on the front lines of ACA enforcement and could increase the amount of guidance it produces and number of audits it conducts, Gerry Griffith said.

''As the IRS reorganization of the exempt organization function is implemented in early 2015 and the IRS continues to clear the backlog of applications for exemption, it will free up resources for other work,'' he said. ''We are also at the point now where clinically integrated networks will begin to show up in years under audit, leading to a renewed focus on hospital-physician joint ventures.''

As nonprofit health-care systems increase in size, geographic scope and diversification of operations, they should expect increasing pressures to justify favorable corporate law and tax treatment under state and federal law, Michael Peregrine, with McDermott Will & Emery LLP, Chicago, said.

''The ability of these organizations to demonstrate their nonprofit, charitable and tax exempt purposes will become particularly important as they cross the $1 billion level in terms of annual revenues,'' he said.

One issue that doesn't appear to be going away is the need for exempt hospitals to satisfy their charity care obligations, Tom Mayo said. ''Even after the ACA is fully implemented—assuming it is not repealed—there will be millions of uninsured and underinsured people, which means 'charity care' will continue as a component of 'community benefit,' '' he said.

With state attorneys general and legislatures investigating and proposing legislation regarding nonprofit health-care executive compensation, Doug Ross said he expects some of the bigger tax compliance issues to arise on the state law side. John Washlick agreed, citing the continuing challenges by states and municipalities to the local tax exemptions of hospitals.

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Quality Metrics, Guidance Needed. Doug Hastings stressed the importance of valid quality and cost measures and said a better understanding of developments in bundled payments and risk-based financing arrangements will be helpful in guiding future antitrust policy.

He suggested that ''payer-provider distrust, antagonism and pricing disputes, if not lessened, will continue to put the onus on government to regulate the prices of both and to manage the contract provisions between them.''

''In addition, as more providers explore and develop 'insurance/risk ventures'—such as forming their own health plan or closely aligning with a health plan—they need to carefully consider antitrust issues in connection with their structure and contractual relationships,'' he said.

Given the level of interest in consolidation and acquisitions, ''the antitrust agencies will have plenty of potential cases to choose from,'' Gerry Griffith said. ''Antitrust is not just a concern for hospital to hospital deals either, as the *St. Luke's* case, to cite one recent example, makes very clear,'' he added.

Mark Waxman pointed to that case and the Massachusetts challenge to the Partners/Southshore hospital transaction as raising important issues with respect to the creation of integrated delivery systems that could be fleshed out in 2015. In that case, a Massachusetts court is considering whether to approve an antitrust settlement that uses price caps to try to rein in potential market abuses following Partners Healthcare System Inc.'s acquisition of rivals South Shore Health and Educational Corp., which operates South Shore Hospital, and Hallmark Health Corp., which operates Lawrence Memorial Hospital and Melrose-Wakefield Hospital.

Doug Ross questioned whether the FTC will accelerate its antitrust enforcement efforts if it wins at the Ninth Circuit in *St. Luke's*. He also said that court's consideration of the provider argument—that antitrust must take a back seat because provider consolidation is encouraged by the ACA—could determine whether the argument gains traction in the courts or Congress.

9. Corporate Governance

The need for health-care organizations to adjust to industry changes and the myriad technical, financial, and compliance challenges facing them are reasons corporate governance ranked as the ninth most significant Top 10 issue in 2015.

More than ever, Tom Mayo said, ''board members will need to roll up their sleeves, ask hard questions of management, and be prepared to make mission-critical decisions.''

''The members of corporate boards are being asked to take on the stewardship of their organizations in a time of profound change and, for many, it will be increasingly both confusing and challenging for them to discern how to appropriately discharge their obligations as a fiduciary,'' Fred Entin said.

Citing the continued consolidation of the nonprofit health-care sector, Michael W. Peregrine, with McDermott Will & Emery LLP, Chicago, said the creation of large national—and in some cases international—highly diversified provider systems will challenge these systems to develop a governance system that is commensurate with the size of the organization.

Honorable Mention: Labor and Employment.

Health-care providers must comply with complex Department of Labor, National Labor Relations Board and Equal Employment Opportunity Commission regulations and enforcement initiatives and are targeted as fertile territory for organizing by labor unions, prompting several board members to rank labor and employment as a worthy honorable mention.

The most significant labor and employment law issue affecting health-care employers will continue to be the NLRB and its ''activist'' approach, said John E. Lyncheski, with Cohen & Grigsby PC, Bonita Springs, Fla. ''It will also continue to build upon its protection of social media content and tie employers' hands in dealing with abuse by employees,'' he said.

''I expect much of the same activism with the EEOC, particularly as concerns enforcement of the Americans with Disabilities Act,'' Lyncheski said.

The biggest change, and the one with the highest profile, will be the promulgation of the so-called ''quickie'' election rule that would significantly expedite the holding of elections following the filing of a petition and tie an employer's hands in a number of respects in terms of its ability to respond to a union organizing effort, Lyncheski continued.

John Doran, with Littler Mendelson PC, Providence, R.I., agreed that the number one concern for health-care employers ''is the expected implementation of the 'quickie election' rules for NLRB elections.'' Although the rules will likely be subject to legal challenges, health-care employers may soon face the possibility of a union election within a couple of weeks of a petition being filed rather than the current six weeks, he said.

Two pending high court cases could affect health-care employers significantly in 2015, Lyncheski said. *Young v. United Parcel Serv., Inc.* (No. 12-1226) involves alleged pregnancy discrimination and *EEOC v. Abercrombie & Fitch Stores, Inc.* (No. 14-86) involves alleged religious discrimination against a Muslim job applicant who planned to wear a hijab or religious head scarf while working.

Katherine Benesch cited the Ebola crisis and the cases in U.S. hospitals that have raised the issue of safety for nurses and others in the health-care workplace. ''These safety issues promise to insert their presence in labor and other employment negotiations with hospitals and large health-care employers in 2015,'' she predicted.

The larger the health-care system, the greater the expectations of focus and engagement will be on their boards. ''Charity regulators, bond rating agencies and other interested parties will increasingly look at the composition and record of the board to see if they are

commensurate with the level of financial and operational sophistication of the health-care system,'' Peregrine said.

Spotlight on Corporate Boards. In addition, regulators, the media, advocacy groups and disenfranchised constituents are looking more than ever at the role of the board in analyzing the cause of compliance, financial, operational and quality of care lapses within health systems, Peregrine said.

The business of governing acute care health systems has become increasingly complex as board governance and industry structure have worked to keep up with the pace of reform and consolidation, Elisabeth Belmont said.

''Significant innovation has occurred in the variety of structures that hospitals and health care systems are using to collaborate and board members must have a general understanding of the purpose and use of each structure, and the factors that influence feasibility, to maximize the outcomes of each of these strategic options,'' she said.

Many health systems are reviewing and reorganizing their governance structure to allow the system to act more nimbly, John Washlick noted.

''As a result of multiple acquisitions over the years, many systems find themselves saddled with multiple levels of legacy boards that have created silos within the system,'' he said.

''Many in this situation are reorganizing to simplify the reporting and accountability of the system subsidiaries and affiliates and when it comes to exploring strategic partners and alternatives, taking the initiative proactively by reviewing their financial position now and projecting it into the future.''

Privacy, Security: Board Attention Needed. Governance issues are corollaries to all other health law concerns, Gerry Griffith said. ''You need an effective compliance program to protect against fraud and abuse, antitrust and tax problems,'' he said. ''Good governance can keep an institution out of the headlines, and for that kind of news, no publicity is good publicity.''

Kirk Nahra said health information and data security issues pose challenges to health-care organizations, and those issues will demand strategic thinking from the corporate boards and leadership.

''I expect increased and ongoing pressure related to cybersecurity risks and similar challenges related to how health care companies use data, with an increased recognition that these are issues that call for board-level engagement,'' he said.

10. Licensure

Licensure traditionally hasn't ranked among the top-tier health law issues for *HLR's* advisory board members, but that changed for 2015, due at least in part to the explosive growth in telemedicine. The issue squeaked into the Top 10 for the first time, ranking 10th.

The paradigm surrounding telemedicine is changing rapidly, according to Dawn Crumel. It can ''function as a driver to increase accessibility and, therefore, is a key factor'' in the success of ACOs and alternative healthcare delivery systems, she said.

Issues with physician licensing, however, have been identified as a barrier to the further growth of the remote practice of medicine. Each state requires physicians practicing there to be licensed by its medical board. A physician licensed in Virginia, for example, may not treat a patient located in Maryland, even through the use of remote technologies, unless he or she also is licensed there.

This 50-state system will have to be ''changed or abandoned,'' Fred Entin said. ''Telemedicine only highlights the need to find a balance between local regulation and efficient care.'' Also implicated are multistate health systems, which might be looking for ways to make it easier for their physicians to move among their hospitals.

''Populations do not begin and end at state lines,'' Entin said. As health-care systems become larger and set up operations in a number of states, and telemedicine gains wider acceptance, ''the question of where the professional is licensed will have to be addressed,'' he said.

Efforts to erase barriers to multistate practice are being made, John Blum said, including proposals that would make it easier for physicians to gain licensure in more than one state. For example, the Federation of State Medical Boards has developed an interstate compact that would provide a one-stop shop for physicians seeking licensure in multiple states, although the compact doesn't mitigate ''the need for individual state licensing,'' he said. Katherine Benesch called the interstate compact model ''the wave of the future.''

Issues concerning physician extenders, such as nurse practitioners and physician assistants, arise in connection with telemedicine, especially in light of physician shortages, Gary Herschman said. Attorneys of doctors who supervise extenders who provide services remotely need to be aware of supervision requirements in other states, he added. Mark Kadzielski said that expanding the scope of practice for such these professionals is a topic to watch in 2015.

By Peyton M. Sturges and Mary Anne Pazanowski

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