

Lead Report

Health Care Policy Top Health Law Issue as Uncertainty Persists

A health-care policy regime that remains in flux, as well as myriad regulatory and business challenges, will test health-care lawyers in 2018 in ways that may have been inconceivable just a few years ago, according to members of Bloomberg Law's Health Care Advisory Board.

Attorneys who advise health industry players are being forced to become fortune tellers, thoughtful business strategists, ethicists, and operational advisers, according to Kirk Nahra, of Wiley Rein LLP in Washington. While being asked to advise on things that aren't really legal issues may be part of the evolution of the legal profession generally, it seems health-care lawyers are at the forefront of the trend, he said.

The trend is reflected in the board's choices for the Top Ten issues they believe health-care attorneys will be facing this year. For example, the number one issue, health-care policy, is more political than legal, but it nevertheless stands to create the most hurdles board members said they will face in advising their clients.

This is the second year in a row health-care policy has taken the top spot. Last year, President Donald Trump took office without a clear health-care policy other than a vow to repeal the Affordable Care Act. This gave rise to widespread uncertainty that in 2018 threatens to devolve into chaos. "The biggest changes in the coming year will likely come from administrative action, or lack thereof," Robert L. Roth, of Hooper Lundy & Bookman, Washington, observed.

Second on this list is fraud and abuse, a perennial fan-favorite that Richard Raskin, of Sidley Austin LLP in Chicago, told Bloomberg Law will keep many health lawyers busy. Fraud and abuse attorneys will have heavy caseloads in 2018, as the "government's pipeline of cases remains deep, and qui tam suits continue to offer significant payoffs," he said.

Health-care industry consolidation came in at number three. The transaction trend "spans practically every sector of the industry, including hospitals/systems, large physician groups, ambulatory surgical centers, payers, and pharmacies," Gary W. Herschman, of Epstein Becker & Green, Newark, N.J., said. Large deals announced at the end of 2017 will keep lawyers busy in 2018 as they move toward closing.

Medicare and Medicaid fell in on the Top Ten list at numbers four and five respectively because of the extent to which providers rely on these government programs for payment. The biggest challenge to Medicare will come from the potential budget cuts necessitated by the Tax Cuts and Jobs Act of 2017. The administration also has singled out Medicaid as a high priority for reform and still is exploring turning it into a block grant program.

Coming in at number six is health information technology. This was at one time a very narrow practice

area, populated by individuals who were highly conversant with the minutiae of the Health Insurance Portability and Accountability Act. However, the explosive growth of this technology, and an increase in the number of high-profile data breach and ransomware cases, have led this issue to intrude on nearly every health lawyer's practice.

According to Gerald M. Griffith, of Jones Day in Chicago, the new tax reform law could lead to a "seismic shift in the landscape for nonprofit health-care systems," putting taxation, and the potential for significant change associated with the issue, at number seven on the Top Ten list.

Corporate governance ranked eighth on this year's list because the need for effective board oversight has never been higher, board members told Bloomberg Law. Michael W. Peregrine, of McDermott Will & Emery, Chicago, said attorneys will have to advise boards on digital health and other evolving issues that could require significant corporate culture change initiatives.

Antitrust and health plan regulation rounded out the Top Ten. Both are closely related to other entries on the list, but merited separate discussion, according to board members.

1. Health Care Policy

Health-care policy took the top spot in the Top Ten for the second year in a row. This will be the most challenging legal issue for health-care stakeholders and their lawyers in 2018, advisory board members told Bloomberg Law, as the policy picture is no less cloudy than it was when Trump took the presidential oath of office in January 2017.

"The Trump administration is using all of its administrative power to undercut the ACA in every possible way."

HOWARD T. WALL III, REGIONAL CARE HOSPITAL PARTNERS, BRENTWOOD, TENN.

While the president's single proposal for reforming health care—repealing President Barack Obama's signature health-care legislation—failed, the administration has been chipping away at key programs and taking actions, like refusing to make cost-sharing reduction (CSR) payments to insurers, all in an effort designed to kill Obamacare.

For health-care attorneys, this means sustained confusion over what rules will govern their clients' businesses in the coming year. It may become difficult to advise on matters such as how to design a practice to maximize reimbursements or how to structure a transaction to avoid antitrust scrutiny. Attorneys will have to be up to speed on every development.

Repeal/Replace. Congress's failed to repeal Obamacare in 2017 and a wholesale legislative change is unlikely in 2018, given widespread disagreement about what a replacement would look like, board members said.

Additionally, a full repeal would mean the demise of provisions popular with the citizenry, like the one that allows parents to keep adult children on employer-sponsored health plans until they reach age 26. D. Brian Hufford, of Zuckerman Spaeder LLP in New York, told Bloomberg Law the "ACA does many important things for consumers, including eliminating the preexisting condition exclusion, expanding ERISA notice and appeal rights to all health-care plans, and prohibiting discrimination based on health or the provider's license." Those provisions would be lost if the law is repealed.

That doesn't mean, however, that Congress will be totally ineffective in setting health-care policy in 2018. John Blum, of Loyola University's Institute for Health Law in Chicago, told Bloomberg Law Republicans may pursue some compromises "to save face in time for the mid-term elections." He thinks there may be movement with respect to the Children's Health Insurance Program (CHIP) and the CSR payments, both of which were on the agenda, but not resolved in 2017.

Hooper Lundy's Roth said he doesn't expect Congress to enact any significant health-care legislation in 2018. Lawmakers more likely will be spending their time in other areas, including the budget and the debt ceiling, he said.

Already Gone. Congress did manage to do away with one of the ACA's most controversial provisions when it included a repeal of the individual mandate—the provision that requires people to pay penalty if they don't have health insurance—in its year-end tax reform bill signed by President Trump.

Without that incentive, healthy people probably won't buy insurance, and premiums for everyone else will increase as a result, Elisabeth Belmont, of Maine-Health in Portland, Maine, said. Any savings gained from eliminating the individual mandate "come entirely from individuals losing health coverage," so health-care providers once again will be asked to care for uninsured and underinsured individuals, she said.

Public hospitals, nonprofit hospitals, teaching hospitals, Medicare providers, and insurers operating on state or federal health insurance exchanges could face "incalculable" harm as a result, Thomas Wm. Mayo, of the SMU/Dedman School of Law in Dallas, said. Katherine Benesch, of Benesch & Associates LLC in Princeton, N.J., predicted the results will be "catastrophic."

Douglas Ross, of Davis Wright Tremaine LLP, Seattle, disagreed, saying, it's hard to see why people are upset. "The mandate was never enforced as such, and the penalties for not buying insurance were set too low to ensure compliance." What remained of the mandate was weakened by the many exemptions issued, he added.

Administrative Action. Any Congressional failure to act on health-care policy, however, will be offset by administrative action, Roth said. Already, for example, the Department of Health and Human Services has issued new rules exempting organizations that object on religious and moral grounds from requirements that they provide employee health plans that cover contraceptives. Although two federal district courts have blocked

those rules from taking effect, the U.S. Supreme Court could ultimately decide to uphold them.

"The Trump administration is using all of its administrative power to undercut the ACA in every possible way," Howard T. Wall III, of RegionalCare Hospital Partners in Brentwood, Tenn., told Bloomberg Law. The ACA isn't necessarily failing, he said. Rather, big drawbacks—like the "slow erosion" of insurer offerings on federal and state health insurance exchanges created under the ACA as a vehicle for the uninsured to acquire coverage—are "a response to the uncertainty that exists over the future of the program."

The "unraveling and dismantling" of health-care regulations, including non-ACA related regulations, "will create more confusion among health-care providers, payers, and suppliers as they attempt to chart a responsible course for the future," Mark A. Kadzielski, of Baker & Hostetler LLP in Los Angeles, said. "The federal health-care bureaucracy will continue to act in unpredictable ways," especially given the departure of former HHS Secretary Tom Price, and the administration's failure to fill many departmental positions at the agency, Kadzielski added.

2. Fraud and Abuse

Fraud and abuse perennially stands as a contender for the top spot on the Top Ten list of issues facing health lawyers. According to advisory board members, 2018 will be no different, with continued emphasis on fraud enforcement surviving much of the upheaval and uncertainty that has plagued the rest of the health-care sector over the past year.

"Fraud and abuse exposure of all types is showing no signs of letting up and, in fact, continues to proliferate," Anne M. Murphy, of Hinckley, Allen, & Snyder LLP, Boston, said.

Richard Raskin agreed, pointing to a significantly increased case load for many fraud and abuse attorneys. Additionally, he said, "the Supreme Court may be due for a follow up to *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 84 U.S.L.W. 4410 (2016), to help lower courts interpret the materiality standard as it applies to alleged violations of a variety of regulatory requirements apart from those governing billing itself," he added.

In *Escobar*, the Supreme Court held that the implied false certification theory can be a basis for False Claims Act liability if the claimant intentionally made specific representations about services provided and failed to disclose noncompliance with statutory, regulatory, or contractual requirements that made representations misleading. The misrepresentation, however, must have been material to government's payment decision, the high court said.

In particular, board members pointed out three aspects of health-care fraud and abuse that should see an uptick in activity for 2018: the enforcement of a rule requiring 60-day repayment of Medicare overpayments, the continued viability of the Stark Law, and some less traditional methods of fraud enforcement that will include commercial insurers as well as federal and state insurance programs.

60-Day Rule. In 2016 the Centers for Medicare & Medicaid Services finalized a rule that required Medicare providers to report and repay any overpayments from the government within 60 days of identifying them.

Recent enforcement efforts and compliance audits however, have shown that implementation of the so-called “60-day rule” will continue to be a topic of interest to health lawyers in 2018, board members said.

“Recent high-profile OIG hospital compliance audits have highlighted the conflicting positions of providers and the government with respect to the obligation to identify additional overpayments following an audit and the appropriate lookback period, given the conflict between the statutory 4-year claims reopening window for Medicare claims and the 60-day repayment rule’s 6-year lookback period,” Doug Ross said.

Sanford V. Teplitzky, of Baker Donelson, Baltimore, agreed, predicting that 2018 would see an increase in both whistleblower actions based on alleged disclosure and repayment failures and aggressive action by providers to investigate internal overpayment reports and to document the good faith and diligence of those efforts.

“At the same time, the real life problem is that many of the situations that may lead to an overpayment are complex and heavily fact-dependent,” he said. “This runs the 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,” he added.

Stark Law. There was some movement in 2017 toward a possible repeal or limitation of the Stark Law, according to Teplitzky. The Stark Law is the name given to the law and regulations that ban physician self-referrals and the creation of new physician-owned hospitals and that place limits on physician compensation.

“...it is possible that the new administration and Congress may actually take action to significantly change and cut back the coverage of the Stark Law.”

SANFORD V. TEPLITZKY, BAKER DONELSON, BALTIMORE

Teplitzky said efforts to reduce negative effects of the Stark Law have been ongoing since a 2016 Senate report that called into question whether the law remains necessary and appropriate, especially in light of its extensive penalties for technical non-compliance. That effort culminated in proposed legislation in 2017 that would have repealed the Stark Law’s compensation prohibitions and reduced them to a prohibition against physician ownership of hospitals.

“In light of continued efforts by the Trump administration to reduce government regulation, it is possible that the new administration and Congress may actually take action to significantly change and cut back the coverage of the Stark Law,” Teplitzky said.

Commercial Insurance Fraud. Medicare Part C, more popularly known as Medicare Advantage, has brought major commercial insurers like United Healthcare and Humana into the business of providing Medicare coverage. But along with receipt of Medicare reimbursement comes the requirement that those insurers submit risk adjustment calculations which could change their payments from the federal government.

According to Jack A. Rovner, of the Health Law Consultancy in Chicago, this requirement could provide a new angle to fraud and abuse litigation with the federal government seeking to recoup overpayments to insurers that provided inflated risk adjustment data. A federal court in California has scheduled a hearing in January to consider whether to allow just such a case to continue against dozens of Medicare Advantage providers. The case is *United States ex rel. Poehling v. United-Health Group Inc.*, C.D. Cal., No. 2:16-cv-8697 (hearing scheduled 1/29/18).

Additionally, board members said 2018 may see an increase in commercial insurers pushing law enforcement to pursue fraud and abuse cases against providers that billed private health plans. “Government focus on more complex, less traditional fraud and abuse schemes, including those that may not involve government payers at all, suggests that providers must be alert and proactive with regard to the identification of problematic issues within their practices and billing professionals,” Jennifer R. Ecklund, of Thompson & Knight LLP, Dallas, said.

3. Industry Consolidation

Health-care industry consolidation continues to be a hot issue for health lawyers. Board members put the issue at number three based on the sheer breadth, volume, and value of the transactions they said they expect to occur in 2018, as well as because of the complicated legal questions they raise.

Katherine Benesch said she expects to see “as many different kinds of agreements for provision of services as health lawyers can dream up.”

Several people thought transaction-related issues should be higher on the Top Ten list, especially given the number of high-profile deals announced at the end of 2017 that are expected to close in 2018. These include CVS Health Corp.’s acquisition of insurer Aetna Inc. for about \$69 billion, as well as the merger of Dignity Health and Catholic Health Initiatives. The latter will create the U.S.’s largest not-for-profit hospital system, with 139 hospitals in 28 states. Other hospital megamergers have been announced between Advocate Health Care and Aurora Health Care and Ascension Health and Providence St. Joseph Health.

The CVS-Aetna transaction involves two of the biggest players in separate industry sectors, pharmacies and health insurance. Brian Hufford told Bloomberg Law the deal will “create a huge health-care entity” with significant sector overlap. Everyone will be watching to see how it plays out and whether the federal antitrust agencies take steps to stop or limit it, though they believe the vertical nature of the deal—meaning the parties don’t compete directly—will be an argument for letting it go through.

The trend toward “horizontal and vertical health system alignment will continue, perhaps with relatively greater emphasis on national or regional consolidation of clinical, ambulatory/outpatient, home health, dental, behavioral, telehealth, and senior living providers,” Anne Murphy said. Industry players will be looking at their attorneys to provide counseling on how to harmonize corporate culture, risk tolerance, and compliance philosophy among multiple care sites, she said.

Physician Sector. Elisabeth Belmont also said vertical, horizontal, and geographic growth will continue as providers try “to create seamless patient experiences,

achieve organizational efficiencies, enhance access to capital, promote innovation, and optimize population health management.”

Major changes in how providers are reimbursed, the growth of clinically integrated and coordinated care practice models, the need for huge capital investments to fund technological innovation, and payer concentration all will drive provider integration in 2018, Gary Herschman said.

Physicians have several options, including joining hospital physician practices, selling their practices to private equity firms, and integrating with national strategic groups and physician practice management companies, Herschman said. Clinical integration, specialty practice acquisition, and the need to build stronger networks drove the process for many years, Mark Kadzielski said.

The impetus for these deals may be changing, however, as “physician exhaustion” now is a big motivator, Kadzielski said. Physicians and physician groups are joining hospitals and managed care groups “to avoid the annoying hassles of running offices, fighting with insurance companies, and handling employee issues,” he said.

Michael F. Schaff, however, told Bloomberg Law he believes the hospital-physician alignment model is losing steam. Early agreements are expiring, and new contracts between doctors and hospitals almost always tie compensation to productivity, he said. Schaff is with Wilentz, Goldman & Spitzer PA in Woodbridge, N.J.

“This has left physicians at a difficult crossroads,” Schaff said. Some physicians will be forced to accept what a hospital offers, as they aren’t in a position to restart their own independent practices. Others will want to venture back out on their own or join mega-practices, he said. Health lawyers can help by carefully reviewing unwinding provisions in physician practice agreements prior to the breakup, Schaff said.

Employed Physicians vs. Medical Staff. Physician-hospital alignments also have led to questions regarding the physicians’ status within the hospitals. Phil Zarone, of Pittsburgh’s Horthy, Springer & Mattern PC, told Bloomberg Law “hospitals are struggling to apply two distinct sets of rules to physicians.”

Many hospitals now have a mix of employed physicians and independent contractor or medical staff physicians as a result of consolidations and alignments, Zarone said. Thus, they must determine if quality or behavioral concerns should be handled through the medical staff peer review process, the employment contract/human resources lens, or both, he said. Physician recruitment also must be coordinated with the medical staff credentialing process, so hospitals don’t waste time recruiting physicians who won’t be granted privileges.

Private Equity and Corporate Practices. Private-equity investments in the health-care field are growing. These investor groups “see value in health care” and can provide the capital providers need to acquire data analytics and population management tools, Schaff said. Attorneys will need to help investors clear regulatory and legal hurdles, like fee-splitting restrictions, licensure laws, and antitrust concerns, he said.

The corporate practice of medicine doctrine, which prohibits corporations from employing doctors to provide medical services, will be a complication in some states. Lowell C. Brown, of Arent Fox, Los Angeles, told

Bloomberg Law he believes some states may weaken corporate practice rules legislatively to accommodate new practice models. Failing that, attorneys will need to find creative work-arounds for their clients.

Although not in effect in every state, the corporate practice of medicine doctrine “has become more and more important in structuring transactions,” Schaff said. Having business people form a management company and provide the property, equipment, staff, supplies, and management services can be beneficial, but “it must be carefully structured to avoid giving the management company control over the medical practice,” he said.

Hospital Sector. Health-care systems that encompass multiple care facilities are quickly becoming the new normal. One question for these systems is whether quality concerns about a physician at one hospital can be shared with another hospital in the same system, assuming he or she practices at both facilities, Zarone said. The question of whether hospitals have a duty to share such information to avoid negligent credentialing or retention allegations persists, he said.

These new megasystems also will need attorneys who can steer them through “the fraud and abuse laws, antitrust laws, Medicare conditions of participation, state licensing regulations, and laws relating to the use and disclosure of protected health information, to name just a few,” Belmont said.

4. Medicare

Board members said one of the biggest changes for Medicare in 2018 is the possibility that it could suddenly become a target for cutbacks necessitated by the Tax Cuts and Jobs Act of 2017 and federal budgets being proposed by the Republican-controlled Congress.

“With the effort by the Republican Congress to cut taxes, there will continue to be pressure to reduce other costs,” Zuckerman Spaeder’s Hufford said. “This combined with the continued focus on repealing Obamacare raises the question of whether there will be a cutback of Medicare, with the inevitable result of millions more becoming uninsured,” he added.

“Further delays in MACRA implementation may occur as physicians continue to push back against the complexities of value-based reimbursement”

JOHN BLUM, LOYOLA UNIVERSITY INSTITUTE FOR HEALTH LAW, CHICAGO

Howard Wall agreed, saying industry groups may need to resort to lobbying for Congressional action as a way to fend off key cuts in reimbursement that will take effect without further legislation. House Speaker Paul Ryan (R-Wis.) “has, as expected, targeted Medicare spending as a piggy bank to fund other programs and make his 10 year budget plan work,” Wall said.

Quality Payment Program. The implementation of a quality payment program mandated by the Medicare Access and CHIP Reauthorization Act of 2015 (MA-

CRA) could be a major issue for health-care providers in 2018, according to board members.

Under MACRA, providers can choose one of two methods for reimbursement in the value-based payment world. The first, Advanced Alternative Payment Model (AAPM), provides health-care providers with incentive payments for taking on some risk related to their patients' outcomes. The second, the Merit-based Incentive Payment System (MIPS), adjusts a physician's payment based on an evaluation against four performance categories.

"Implementation of MIPS will take on increasing importance as physicians begin to feel the consequences of performance-based payment cuts," Kim H. Roeder, of King & Spalding LLP, Atlanta, said. "Many physicians and groups remain ill-equipped in their understanding of and response to this complex reimbursement system. Significant portions of the market have not yet evolved to a sufficient level of risk to qualify under alternative payment models and avoid MIPS," she added.

John Blum agreed that physicians' lack of preparation for the MACRA reforms could lead to the HHS pushing back its expected compliance dates.

"Further delays in MACRA implementation may occur as physicians continue to push back against the complexities of value-based reimbursement," he said. "Only 38 percent of physicians are expected to participate in MIPS, making reform far slower than anticipated, and sparking tension among those who have complied," he added.

Any lag in MACRA program participation could cost what John R. Washlick, of Buchanan Ingersoll & Rooney in Philadelphia called successful efforts to implement bundled payment programs. "The success of these programs relies on provider adoption of these new payment models," he said. "However, as many providers are preparing to participate in the value-based world, the Trump HHS shows signs of stepping back from some of these initiatives started by the Obama administration, at least for the short-term, to allow physicians and providers to be more engaged in the process of setting standards and at a minimum to participate in defining quality."

Additionally, according to Anne Murphy, the expected implementation of MACRA could mean 2018 could see substantial growth in telehealth and scientific innovations in the health-care space. "We may see greater relative focus on quality metrics associated with research trials, telehealth and bundled service delivery," she said. "I also believe there are scientific and technology advances that may impact the standard of care—for example, simulation for surgical and procedure training, and personalized medicine with greater accuracy in diagnosis and treatment," she added.

5. Medicaid

Medicaid will continue to be a prime force as health-care policy evolves and affects how health lawyers counsel clients in 2018, according to board members. However, what shape the program will take in the new year is as uncertain now as it was one year ago.

"CMS Administrator Seema Verma has indicated that Medicaid reforms are a high priority for the administration," Bob Roth said. "She has significant administrative and regulatory tools at her disposal to effect major change and, ironically, some of this flexibility, espe-

cially allowing work requirements in Medicaid, could lead some states to adopt the Medicaid expansion option under the ACA."

Block Grants. One major way that Medicaid could be altered in the new year is if federal funding to states is provided via block grants and per capita caps are applied. According to board members, such a change could have a major effect on the survival of the program.

"Medicaid funds the health-care costs on the order of a third of all Californians," J. Mark Waxman, of Foley & Lardner, Boston, said. "In other states, the system is also dependent on Medicaid dollars and if those dollars are interrupted, or materially decreased, the system will once again be on the verge of collapse," he added.

Managed Care. Any decrease in funding to the states or change to the manner in which that funding is distributed could force states to rely more heavily on managed care models as a way of administering their Medicaid programs. "The push to block grant Medicaid will continue, giving individual states great leeway to redesign their programs, sparking even greater dependence on commercial managed care arrangements," Blum said.

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ROBERT L. ROTH, HOOPER LUNDY & BOOKMAN,
WASHINGTON

Under a managed care model, a private managed care organization (MCO) assumes the risk that Medicaid participants will have more costly illnesses than expected. It does this by accepting a capitated payment from the state Medicaid agency for the Medicaid-eligible patients the organization covers. If a patient incurs lower costs than the expected average patient in a given year, the MCO keeps the extra amount as profit. If the patient incurs greater costs, the MCO must eat those extra costs and can't seek additional payment from the state Medicaid agency.

According to Jack Rovner, states will likely feel greater pressure to adopt managed care systems as a way of offloading the risks involved in any Medicaid transformation from the CMS.

However, Howard Wall said regardless of political changes, he expected health-care provider groups to fight for expanded Medicaid benefits in 2018. "Despite the continuing calls in Washington for repeal and replace and efforts to turn Medicaid into a block grant program, look for provider industry groups to continue the fight to keep expansion in place and to preserve the safety net that the program provides to many working poor," he said.

6. Information Technology

Health information technology encompasses a broad range of activity in the health-care space, according to Kirk Nahra. "While originally a niche practice, these kinds of data management, data analytics and technology issues now arise virtually everywhere in the health-

care field, and in a very broadly defined health-care field,” he said.

In particular three major pillars of the health-care world involve information technology and promise to be top issues for health lawyers in 2018: telemedicine, cybersecurity, and HIPAA enforcement.

Telemedicine. Telemedicine saw a huge surge in 2017 with more and more states passing laws to allow reimbursement and licensing for telemedicine providers. According to board members, that effort has just begun. “Telemedicine will continue to shape the licensure and scope of practice rules during 2018 as federal and state regulators struggle to keep up with this emerging trend,” Michael Schaff said. He pointed out that the first license under the Federation of State Medical Boards’ Interstate Medical Licensure Compact was issued to a telemedicine provider in April 2017. By October, 22 states had adopted the compact in some form.

In addition to licensure issues, board members pointed to reimbursement and the use of mobile technology as additional concerns with telemedicine in 2018. “The tremendous expansion of virtual medicine through practitioner visits made possible by telemedicine is dynamic uncharted territory for health lawyers,” Mark Kadzielski said. But, he added, “despite the expansion of state telehealth compacts, the lack of any comprehensive federal coverage will continue to be a sore spot for this growth area.”

According to Teplitzky, stakeholders and legislators have encouraged the Medicare and Medicaid programs to follow the lead of the Veterans Health Administration by supporting legislation that increases coverage and reimbursement for telehealth services.

Cybersecurity. HIPAA compliance and the dangers of health-care data breaches are of primary concern for health lawyers in 2018, according to board members.

“As health-care providers are faced with the rapidly evolving technology in their operations, they are exposed to ever-increasing risks of data breaches involving patient health information, civil penalties for violating the HIPAA Privacy and Security Rules, potential lawsuits by affected patients as well as loss of confidence by patients,” Schaff said.

According to Katherine Benesch, a number of the data-related events in 2017 should cause many health-care providers to focus more attention on the security of their data. “The huge data breaches, and cyber-pirates holding British hospitals hostage, do not bode well for health-care institutions,” she said. “Given the many financial uncertainties facing hospitals in the U.S. in 2018, incurring substantial expenses to beef up cybersecurity is the last thing hospitals need,” she added.

Elisabeth Belmont pointed to the ransomware attack as something that health-care providers should watch, not just because of the disruption to business, but also because it could be the basis of an enforcement action. “Since a ransomware attack is considered a breach by the HHS Office for Civil Rights unless the entity can demonstrate a low probability that PHI has been compromised, health-care providers should pay particular attention to this threat,” she said.

According to Nahra, HIPAA requirements and cybersecurity statutes and regulations provide a complex web of rules that are essential for a health lawyer in 2018 to understand. “The best lawyers in this area—and the most successful companies—will need to have a practical and detailed knowledge of this confusing legal

structure, and be able to navigate an increasingly complicated business environment in the context of an uncertain regulatory and enforcement structure were there are increasingly broad gaps,” he said.

HIPAA Enforcement. The HHS Office for Civil Rights was “strangely quiet in 2017,” following a flurry of enforcement activity in 2016 involving HIPAA, which protects the privacy of protected health information, Reece Hirsch, of Morgan, Lewis & Bockius LLP, San Francisco, told Bloomberg Law. In 2018, we should find out if this is “the new normal,” he said.

“Telemedicine will continue to shape the licensure and scope of practice rules during 2018 as federal and state regulators struggle to keep up with this emerging trend.”

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

“Now that HIPAA Phase 2 desk audits have been concluded, it will be interesting to see how OCR assesses the state of the industry’s compliance with HIPAA, and how the identified deficiencies are reflected in a future enforcement actions,” Hirsch said.

Hirsch also noted that there are “gray areas” regarding which agency—OCR or the Federal Trade Commission—has jurisdiction over issues that arise under HIPAA. OCR in 2016 provided some useful guidance, but these issues “must be hammered out in the marketplace,” given the “enormous digital health innovation” occurring, he said.

7. Taxation

How the recently-passed tax reform bill will affect hospitals and health-care providers will be a major issue for 2018, board members said.

Jones Day’s Griffith warned that tax reform could threaten the already thin margins of hospitals by eliminating the individual mandate, taxing a variety of employee benefits, increasing exposure to unrelated business income tax, and adding a significant excise tax burden on any health-care organization forced to compete for highly compensated talent.

But many board members said compliance with tax Code Section 501(r) requirements could cause the biggest upset in 2018. “Practitioners have seen and will see more IRS adverse actions against tax-exempt hospitals stemming from IRS reviews of community benefits provided by exempt hospitals required by the Affordable Care Act,” T.J. Sullivan, of Drinker Biddle & Reath LLP, Washington, said.

Tom Mayo agreed, saying local taxing authorities could “double down” on nonprofits deemed to provide an insufficient amount of community benefit. “The economic recovery, though impressive, continues at a sluggish rate; states are strapped for cash, and most public services are provided by city and county governments,” he said. “There hasn’t been a flood of filed cases, but nonprofits will be keeping their eye on the compliance ball, including compliance with the ACA’s additional requirements under IRC § 501(r).”

According to Michael Peregrine, this renewed focus on Section 501(r)'s community benefit requirements could cause hospital boards to oversee their compliance departments more closely out of fear that IRS enforcement actions could result in a revocation of the hospital's tax-exemption. "Boards are being called upon to focus more closely on compliance with exempt organization tax law following a series of public actions by the IRS, including two separate actions to revoke the tax-exempt status of a nonprofit hospital, and the release of guidelines that demonstrate the areas of focus in tax audits of charities," he said.

8. Governance

Corporate governance almost always lands a spot in the Top Ten. Board members predicted technological changes, industry consolidation, and evolving enforcement priorities will challenge corporate boards.

Governance lawyers—both in-house and outside counsel—"will need to prompt and guide" the discussion that will follow from the overall uncertainty facing the health-care industry in 2018, Kirk Nahra said. Company boards must be attuned to "the full array of issues that must be managed to remain a successful company," he said.

Technological changes will be a large driving force behind many governance issues in 2018, Michael Peregrine told Bloomberg Law. Digital health-care developments, such as the entry of Silicon Valley firms into traditional health-care fields, have the potential to disrupt traditional health-care company business models, he said. Attorneys advising the companies must be up to the challenge.

Additionally, the increased "adoption of emerging technologies" by providers "presents significant risk oversight challenges for health-care system boards," Elisabeth Belmont said. "Board directors should develop an understanding of how such technologies will be utilized within their own system, and the role that such technologies play in accomplishing the system's strategic goals" in order to comply with their fiduciary duties, she said.

Health information technology developments "create significant opportunities" for providers, but "also may alter the risk profile," Anne Murphy agreed. Governing boards should be aware of and prepared to act on those issues, she said. Reece Hirsch noted that "health-care records provide a rich target for cybercriminals" and advised health-care organizations to "raise their game with respect to cybersecurity." Those efforts "should begin with the board of directors," he added.

The board can do a great deal to limit an organization's exposure, Hirsch said, even though some boards have been reluctant to tackle cybersecurity because they think it is beyond their knowledge and experience.

Companies will need board members and a leadership structure capable of "promptly, thoughtfully, and creatively dealing with constant turmoil, ongoing technological change, a regulatory and enforcement environment with tremendous uncertainty, and the need for advice and guidance in growing areas where regulation is largely absent," Kirk Nahra said.

Consolidation's Effects. Consolidation and integration within the health-care industry "will make governance even more important in the future," Mark Kadzielski said. "Integrating different organizational

cultures, especially when spread across several states or through disparate regions, is neither easy nor quick."

The board's composition also will be important, Kadzielski said. Having physicians on the board can be a plus, but also may be a drawback, depending on the individual. But "the days of honorary board members who rubber-stamp management decisions are past," he said.

The board's role in developing and promoting a positive corporate culture will be emphasized in 2018, following two 2017 developments that sounded a wake-up call, board members said. The "Holder Report," compiled by former U.S. Attorney General Eric Holder, was issued in June 2017 following an investigation into an allegedly harassing culture at Uber. The report deemed culture a corporate asset. The fallout from Hollywood's Harvey Weinstein sexual harassment scandal also will be on the minds of corporate board members as they review and implement new policies.

Technological changes will be a large driving force behind many governance issues in 2018.

MICHAEL W. PEREGRINE, MCDERMOTT WILL & EMERY,
CHICAGO

Health-care companies can learn lessons from both events, although neither involved the health-care industry. "Highly publicized scandals involving toxic corporate cultures, in some cases with sustained sexual harassment by executives, requires boards to be assured that the health-care organization has tools in place to detect and respond to inappropriate behaviors," Anne Murphy said.

Individual director liability also still is a concern, especially in the area of cybersecurity, Peregrine said. The Department of Justice may no longer emphasize individual prosecution, as urged by the 2015 memorandum issued by former U.S. Attorney General Sally Yates, but that doesn't mean "the government's focus on individual liability has lapsed," he said. Doug Ross also advise that boards shouldn't dismiss the Yates memo, despite "mixed signals" from the Trump administration.

9. Antitrust

Antitrust appears low on the list, but that doesn't mean it isn't an important issue for 2018. The trend toward industry consolidation and integration is bound to catch the eye of federal enforcers, who could start looking closely at all the deal activity in the sector.

Antitrust enforcement "is the last line of defense" against deals that ignore the evidence and experience that underlie antitrust policy—that is, that competition "results in better quality at lower cost, while private market power seeking to dictate what's 'best' for consumers does not," Jack Rovner said.

The "cost and difficulty of antitrust enforcement," however, "limits that defense's effectiveness," he added.

Government antitrust enforcement, moreover, "is more of a wild card than in most years," Richard Raskin

told Bloomberg Law. “The current administration has not yet shown its hand” with respect to its enforcement policy, especially in the health-care sector. The direction antitrust enforcement will take “remains to be seen,” Gerry Griffith agreed.

Raskin said “it’s safe to assume” the antitrust agencies will “stay the course,” focusing on drug makers’ pay-for-delay settlements and provider consolidations, though “it will be interesting to see if something more explicit emerges in the coming months.” An increase in private antitrust actions can be expected, he added.

Government antitrust enforcement “is more of a wild card than in most years.”

RICHARD RASKIN, SIDLEY AUSTIN LLP, CHICAGO

Mega-health systems could be a target, Gary Herschman said. In many cities, hospitals already have “picked sides.” John Blum agreed that large health system consolidation “will heighten the specter of antitrust enforcement.”

To escape antitrust review, dealmakers will be looking to form new regional or multi-regional megasystems outside their traditional geographic markets, Herschman predicted.

Consolidation in the physician practice sector may attract enforcers’ attention, but that ignores the reality that government programs like the MACRA are putting pressure on doctors that is driving them to sell practices to health systems and large corporate groups, Doug Ross said.

The Federal Trade Commission “refuses to acknowledge the reality that requirements imposed on physicians by its sister agencies mean, like it or not, that the days of many small independent groups practicing medicine in the U.S. are over,” he said.

Ross added that state attorneys general “may jump into the fray” and challenge these physician practice consolidations under state law.

Jennifer Ecklund told Bloomberg Law there may be a “sea change” in the types of mergers ultimately approved by the federal agencies. Combinations of pharmacies, patient care providers, and insurers will expand the reach of these health-care entities.

Similarly, Mark Waxman predicted an “increased focus on vertical integration”—that is, more mergers between players that don’t compete in the same market sector, like payers and providers.

Health-care industry players want “to deliver a ‘complete product’ or ‘integrated platform,’ and the courts will continue to explore just what that means,” Waxman said.

Still, “there remains no substitute for market power,” Waxman said. “Successful market positioning requires knowledgeable guidance in advance to avoid price-fixing, tying, and other prohibited market power claims,” he said.

10. Health Plan Regulation

Health-plan regulation won a spot in the Top Ten this year due to the amount of turmoil that is roiling every segment of the health insurance industry. Creative law-

ying will be required to steer insurers through the curves, board members said.

The turmoil in the health insurance sector has been caused by “magical thinking divorced from business and market realities.” Jack Rovner told Bloomberg Law. It likely will continue, if not get worse, in 2018, he said.

Looking at individual insurance sectors, Howard Wall said he expects private employer-sponsored health plans to shift more costs to their members by offering high-deductible, high-copay plans. Brian Hufford expects to see questions arise over regulatory oversight of self-funded plans.

Still, people who have employer-sponsored plans will be far more fortunate than individuals looking to obtain health plans through the federal and state insurance marketplaces established under the ACA. Several insurers have pulled out of unprofitable marketplaces for 2018, while others have raised deductibles to unaffordable levels.

Restrictions on individual consumer choice in plans sold on exchanges will result in “very costly or deficient insurance products,” John Blum said. The lack of competition in some areas, along with the repeal of the ACA’s individual mandate, is expected to result in lower subscription rates, higher premiums, and the replacement of comprehensive health coverage with low-cost “skinny” or catastrophic coverage-only plans. That could be bad for providers, who once again will see their emergency rooms filled with underinsured or uninsured people, John Washlick said.

Tensions between payers and providers also may amp up, especially when it comes to coverage for services offered by out-of-network providers.

D. BRIAN HUFFORD, ZUCKERMAN SPAEDER LLP, NEW YORK

“A key question” for 2018 “is whether the government will act to stabilize the exchanges, at least until an alternative can be put into place,” Hufford told Bloomberg Law. “Figuring out a way to address high insurance premiums,” for example, “remains a key priority,” he said.

Tensions between payers and providers also may amp up, Hufford said, especially when it comes to coverage for services offered by out-of-network providers. Insurers could wind up with “tremendous discretion” in setting limits on the types of treatments they will cover. Alternatively, patients could be left responsible for a greater percentage of the bill—an issue over which there already has been a great deal of private litigation.

Trump administration proposals, such as allowing insurers to sell products across state lines and narrowing ACA coverage mandates will require state action, meaning attorneys must be familiar with regulations in multiple states, board members said.

The health-care industry “will face enormous challenges in 2018 to stay on top of these developments and navigate the ongoing challenges of remaining viable

and successful businesses while still maintaining some kind of public trust,” Kirk Nahra said. He sees “an enormous need for planning, strategic guidance, risk management, and even a broad role in public relations” facing lawyers in the coming year.

Some insurers, faced with these challenges, may “seek new models for their businesses,” such as pushing plan members to use digital options, like telehealth, Lowell Brown said.

Other insurers will continue their strategy of moving into the provider space through acquiring physician practices and facilities. These moves “reflect a sector restructuring as it positions itself to survive and thrive in a changing health-care delivery system,” Wall said.

Wild Card: Drug Regulation

One aspect of the coming year for health lawyers that many of the board members listed as a concern, but that didn’t fit into the Top Ten was the efforts to curb the opioid abuse epidemic.

“The opioid crisis has created a host of legal challenges for health-care providers, such as helping ad-

dicted employees; adopting policies to prevent, investigate, and report diversion; responding to police requests for tests and body cavity searches; and conducting searches and seizures of patients and visitors suspected of possessing contraband,” Phil Zarone said.

Elisabeth Belmont said 2018 should see additional resources on both the state and federal level expanded to fight the epidemic. “The severity of the opioid-overdose crisis has led to some of the first emergency declarations for a non-communicable health condition,” she said. “It is noteworthy that at least six states have taken the unusual step of using their legal authority to declare the opioid-overdose situation an emergency,” she added.

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