Our Insights into Healthcare Industry Trends

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2017

The only certainty in healthcare for 2017 is change. The forces for change are driven not only by politics, but also by economic factors, clinical needs and technology advancements (and associated risks).

Given the rallying cry of "repeal and replace" in the 2016 election, all eyes will be on the direction of private insurance market reform as the Trump Administration takes office. But even tougher and more politically charged questions may arise as the Republican administration and Republican-controlled Congress take on questions of structural reform to Medicare and Medicaid.

Our King & Spalding healthcare practitioners are closely watching the developments in Washington that affect healthcare payment and spending. But there are significant additional trends – influenced by economic realities, the ever-dominant regulation that affects healthcare, and new technological directions – that we consider vital for our clients and that we are reporting on here as we share our insights.

We look forward to our continued work with our valued healthcare clients in 2017. We hope you find the insights shared in this booklet helpful as you plan for the success of your organization in 2017.

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Editor

The New Administration and the Future of the Affordable Care Act

Major programs enacted by Congress often get amended, sometimes repeatedly. Laws relating to Social Security, federal civil rights protections and immigration are examples. In 2003, Congress enacted a new Medicare Part D prescription drug benefit, and four years later amended that statute with a technical corrections bill. The Affordable Care Act was certainly major, complex legislation, but it has not yet been amended in a substantial or comprehensive way. With one party controlling the executive and legislative branches, we will see changes, and they will likely not be the last ones.

"Repeal and replace" has become a political rallying call, and Congress is actively implementing "repeal" before "replace" is fully known. We expect in the replacement aspects to see certain fundamental principles of the ACA preserved. The possibility of differing State solutions will be increased, but the importance of healthcare access and affordability as a national issue will be reaffirmed, and significant federal intervention in health insurance and healthcare financing for working families will continue.

- Healthcare costs have increased and will continue to increase at a faster rate than the earning ability of many citizens, so federal financial assistance to assist low-income households in purchasing insurance coverage will continue. Tax credits, to be used to purchase private insurance coverage and to fund Health Savings Accounts, are the likely successor to the current approach.

- Denying affordable coverage to people with serious health conditions, just when they need it the most, is no longer acceptable, so mechanisms extending coverage to persons with pre-existing conditions will continue.

- Product designs that allow dependent children to remain on their parents' coverage long enough to complete college or get started in a career are very popular, and federal requirements making these products available will continue. Prohibitions on products with unreasonable lifetime maximums will also continue.

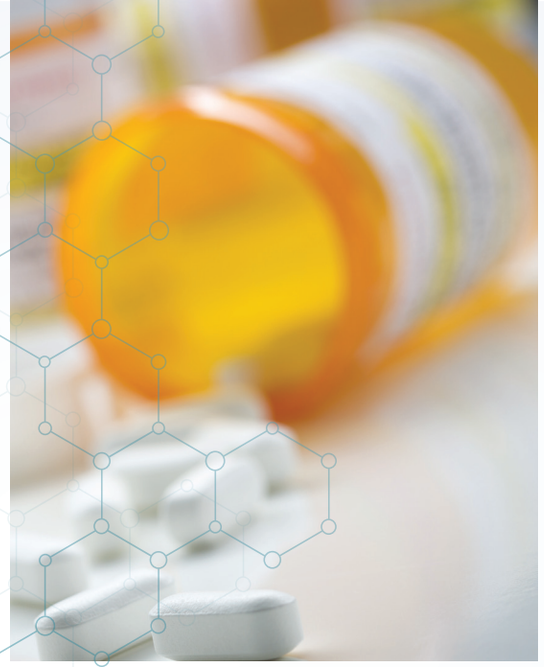
- Insurance markets required to provide coverage to persons with serious health conditions can be stabilized by funding high-risk pools. Federal funding of such pools is likely, continuing a significant role for federal revenues in stabilizing insurance markets.

- Insurance products are subject to complexities that can confuse consumers. While a wider range of products – some of which will permit consumers to take short-term risks – are likely to be permitted, required standardization and mandated disclosures to assist consumers in making wise choices will continue.

- Actual experience with the ACA and prior experience in certain States has shown that insurance solutions cannot work over the long term if consumers do not participate continuously over a long period, even when they are not in need of insured services. The current individual mandate will be repealed, but other means of incentivizing consumers to purchase and maintain coverage continuously will be enacted. Rates could be made much higher for those who have let their coverage lapse and wish to regain coverage, and there might be no opportunity to regain coverage at all except during widely spaced open enrollment periods. Default enrollments of persons who do not enroll themselves into a catastrophic plan also might be part of this.

- Mandated pricing, which finances the needs of older consumers by requiring above fair market value prices for coverage for young consumers, will be relaxed in ways that will encourage continuous coverage at all age levels. The inescapable fact of much-higher average costs of coverage for older persons than for the youngest will be addressed more directly, possibly with tax credits adjusted based on age and not just income.

- A federal requirement allowing insurers to sell their products in States in which they are not licensed, apparently using federal preemption principles to overrule States that do not agree, is a paradoxical proposal when urged by conservatives. Expressions of support for this have been widespread and have included the new President, so providers may soon have a number of smaller companies from other States seeking to contract with them. >>



"The general public and the news media forget that the ACA also made major changes to Medicaid and Medicare. Support for 'repeal and replace' the ACA is also creating the possibility of another round of major reforms of Medicaid and Medicare."
– Allison Kassir, Government Relations Advisor, King & Spalding

Major programs benefit when they have elements that are appealing across a broad political spectrum. Several Senators have expressed the need for bipartisanship to ensure a durable approach to healthcare. While some components of "repeal and replace" can be accomplished through the budget reconciliation process, a procedure which expedites legislative consideration, other reforms must be considered under standard legislative procedures. Will we see bipartisanship in decisions over the successor to the current ACA and restraint on the use of the filibuster rule to oppose changes by the minority in the Senate? Electoral facts point to this possibility. A filibuster cannot be maintained in the new Senate if the minority loses eight votes, and 13 Democratic Senators will be up for reelection in 2018 in States won by President Trump. There is precedent for Presidents to raise money for and campaign for candidates in Senate races. Democrats wanting to regain a majority in the Senate may find that bipartisanship on the part of at least some of their members is a practical requirement.

While there is a concentrated focus on the differences between political parties, it is important to remember that the most interesting battles in Washington often occur between the two chambers of Congress.

According to James Madison, the Constitution's framers considered the Senate a "necessary fence" against the "fickleness and passion" that characterized the general public and approach of the House of Representatives. George Washington reportedly told Thomas Jefferson that the Senate was created to "cool" House legislation, as a saucer was used to cool hot tea. We expect to see this dynamic play out in the legislative debates to enact a replacement to the ACA.

A related question is whether action on the ACA, or on other priorities of the new President, will lead to modifications or elimination of the filibuster rule itself. A combination of precedent set by past modifications, a reduction of comity in Congress, and what has been described as a historical "change" election could lead to this type of change as well.

The general public and the news media forget that the ACA also made major changes to Medicaid and Medicare. Support for "repeal and replace" is also creating the possibility of another round of major reforms of Medicaid and Medicare.

"The Affordable Care Act was certainly major, complex legislation, but it has not yet been amended in a substantial or comprehensive way. With one party controlling the executive and legislative branches, we will see changes, and they will likely not be the last ones."
– Glen Reed, Partner, King & Spalding

- Medicaid in particular is an element of the coverage accessibility features of the ACA, so necessary changes in Medicaid will make the potential for broader program reforms likely. A major devolution of authority to the States could happen, with a corresponding set of new challenges to policymakers in every State. Many changes would not require legislation; the Trump Administration could immediately provide greater waiver authority to the States.

- Medicare is on a trajectory toward value-based payment, a concept with such broad support that it is unlikely to be disrupted significantly. Power over Medicare is likely to be taken back by Congress through elimination of the Independent Payment Advisory Board (IPAB). However, there is some argument for keeping the IPAB process, which is not repealable through a reconciliation process. If the IPAB process is triggered but the IPAB is not appointed, the HHS Secretary would be vested with the authority to make cuts.

- Beyond that, Medicare reform deliberations will raise the broader issues of deficits, national debt and entitlement reform. Medicare has proven a potent political rallying point. Major reforms, such as a premium support system to shift Medicare further into the use of insurance products, may be delayed while other actions are given a chance to boost the economy and tax revenues.

The size of the uninsured population, on a State-by-State basis, will require attention as these changes are made. ACA payment changes that reduced Medicare payments to hospitals based on unrealized projections about reductions in uninsured patients have created significant stresses on some hospitals, particularly in States that did not expand Medicaid in accordance with those projections. Some aspects of ACA reforms and State-directed Medicaid reforms could increase somewhat the number of uninsured patients, and so a recalibration of Medicare payments to hospitals will be in order and will likely be considered. ♦

Complex Enforcement & Compliance Environment

An expanding universe of interested "examiners" is scrutinizing organizational compliance. For example, in November 2015, the Department of Justice (DOJ) retained a compliance expert to help the DOJ assess the effectiveness of an organization's corporate compliance program.

Fueled by legal and regulatory developments, the sophistication of the techniques used by the examiners, and the examiners' ability to establish noncompliance and obtain significant recoveries, have increased. Further complicating the landscape, the Centers for Medicare and Medicaid Services' (CMS') issuance of the Medicare Parts A and B Overpayment Rule in February 2016 adds significant pressure on healthcare providers to pursue a diligence to analyze potential overpayments. Failure to comply with hte Overpayment Rule is enforced throught the False Claims Act and on August 1, 2016, statutory penalties under the False Claims Act nearly doubled, from a minimum per claim amount of $5,500 to $10,781 and from a maximum per claim amount of $11,000 to $21,563.

Expanding Universe of "Examiners"

The traditional enforcement community continues to play a key role; however, the universe of examiners is rapidly expanding.

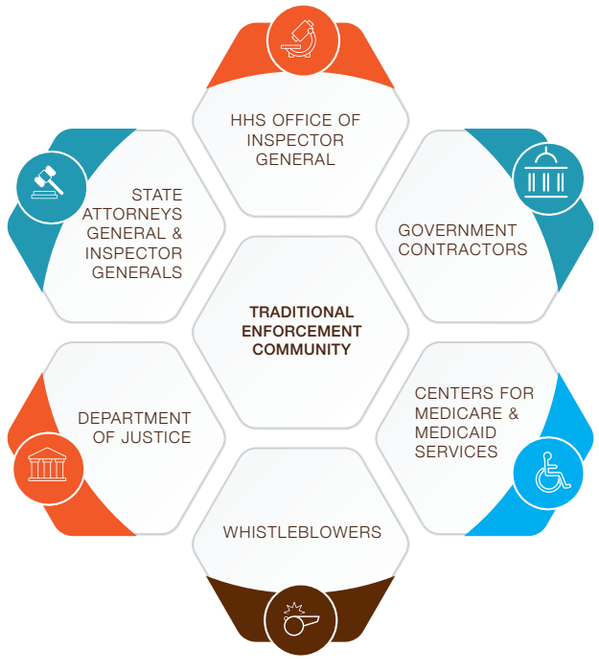
Whistleblowers continue to play a significant role in this regard, and the whistleblower community is no longer limited to disgruntled employees.

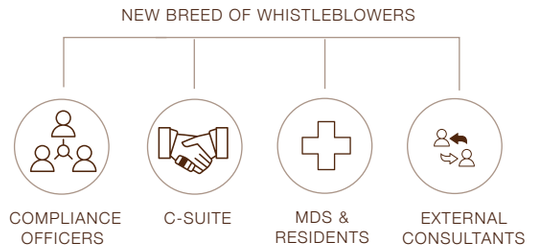
There were 845 new *qui tam* suits filed in federal fiscal year 2016; 702 of those actions were brought by whistleblowers. In total, $4.7 billion was recouped.

A new breed of whistleblowers includes senior management, physicians, compliance officers and consultants engaged to assist with proactive compliance efforts.

Further, experienced whistleblower counsel actively recruit whistleblowers and are often the party that effectively prosecutes the cases (including cases in which the government has declined intervention). In federal fiscal year 2016, approximately $100 million was recovered in *qui tam* cases where the government declined intervention.

In addition to the traditional enforcement community, numerous other third party stakeholders are examining institutional compliance in the healthcare industry. For example, business and finance partners are performing more exacting diligence with respect to the sophistication of compliance programs and the inventory of ongoing compliance matters in order to evaluate financial risk. >>





"In response to the government's emphasis on individual accountability, there will be a significantly larger number of civil and criminal actions brought against responsible individuals.We are seeing this complicate the resolution of investigations and litigation against corporate entities.We also expect the universe of whistleblowers will increase even more dramatically as those under the microscope point the finger at others to deflect scrutiny."
- Michael E. Paulhus, Partner, King & Spalding

How Have the Government's Expectations Changed?

Active Compliance Program Tailored to Specific Risk

↓

Mature Compliance Infrastructure with Continuous Efforts to Assess and Enhance Program

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Centralized and Disciplined Risk Assessment Program with a Strategic Effort to Assess, Identify and Prioritize Risk

Enhanced Focus On Criminal and Civil Enforcement Against Responsible Individuals

The traditional enforcement community is expected to be more hands-on in their focus on identifying individuals who may have contributed to the conduct under review.

- The Yates Memo, issued in September 2015, announced that the DOJ would seek accountability from the individuals involved in corporate misconduct, and for an organization to qualify for any cooperation credit, the organization "must provide to the DOJ all relevant facts relating to the individuals responsible for the misconduct."
- In FY 2016, HHS Office of Inspector General (OIG) excluded 3,635 individuals and entities from participation in federal healthcare programs.
- Thus far, the DOJ's national takedown efforts have resulted in charges against almost 1,200 individuals for more than $3.4 billion in fraudulent billings.
- *U.S. v. Tuomey Healthcare System Inc.*: A CEO of a healthcare system agreed to exclusion and a $1 million settlement to resolve alleged violations of the Stark Law and the False Claims Act.

Enhanced Expectations for Compliance Programs and Risk Mitigation Efforts

The government's expectations with respect to compliance program effectiveness and risk assessment and mitigation efforts have increased dramatically over the past several years. In April 2015, OIG and industry leaders released "Practical Guidance for Health Care Governing Boards on Compliance Oversight." This multidisciplinary publication aims to provide the governing boards of healthcare entities with resources to carry out their oversight obligations of institutional compliance.

An organization's compliance program is expected to be well-resourced and include an active risk assessment component. The government no longer views the compliance officer as solely responsible for institutional compliance. For example, OIG now requires members of senior management – not just the compliance officer to certify compliance with Corporate Integrity Agreement obligations. Additionally, senior leadership and the board are expected to be engaged in the compliance program efforts and oversight, as well as support the compliance officer.

Examiners Have Powerful Weapons, Investigative and Auditing Techniques, and Innovative Theories of Recovery

Examiners have a broad array of tools to utilize during the audit and investigative period, including the authority to implement significant recoupment efforts before the merits of a case have been established (such as the implementation of payment suspensions or recoupment of the alleged overpayment).

During an investigation, examiners will not only be assessing the specific underlying conduct at issue, but will also be assessing the organization's efforts to implement an active and effective compliance program that is well-designed to mitigate risk.

- On April 18, 2016, OIG published criteria that it will consider when evaluating persons or entities for permissive exclusion under Section 1128(b)(7) of the Social Security Act. OIG will use a "risk spectrum" to determine the appropriate remedy, ranging from a release to exclusion from federal healthcare programs, depending on the facts and circumstances and the level of risk the person or entity poses to federal healthcare programs.
- HHS Inspector General Daniel Levinson, in his remarks at the Health Care Compliance Association's Annual Compliance Institute in April 2016, stated, "You get no bonus points for having a compliance program." Instead, the absence of an effective compliance program indicates higher risk.

The standards for evaluating compliance program effectiveness are fluid, and are not necessarily applied consistently by the enforcement community. For example, whereas HHS OIG formerly touted seven elements of an effective compliance program, the agency seems now to be particularly focused on the importance of voluntary self-disclosure efforts. ♦

"It is no longer sufficient for a healthcare organization merely to maintain an elemental compliance program. Instead, the government requires the organization to maintain an effective, independent, collaborative, and well-resourced compliance program that is able to proactively identify, evaluate, and mitigate the organization's risk."
- Sara Kay Wheeler, Partner, King & Spalding

Healthcare Mergers, Acquisitions and Other Transactions

"Healthcare transactions, like the industry itself, are continuing to increase in complexity. Creative structures including joint operating companies, integrated networks, service line joint ventures and management service organizations are being utilized by providers and non-providers alike to address market forces."

- Jon Harris, Partner, King & Spalding

Overall

- M&A and other transaction activity in healthcare and life sciences increased throughout 2016. We expect activity to increase further in 2017 as potential changes to healthcare reform become clearer under the new administration.
- Long-term fundamentals such as an aging population, cost pressures and reimbursement changes will continue to drive activity and investment in healthcare. The overall impact of the likely repeal of the Affordable Care Act is unclear, but it is probable that the factors driving providers to consolidate and find efficiencies will remain. Some sectors will stand to gain while others will lose.
- Global healthcare M&A deal value in 2015 exceeded $546 billion, a 30+% increase over 2014. Through Q3 2016, deal volume in 2016 is up 5.5+% over the same period in the prior year.

Effects of 2016 Election

- It is unclear wheather Republicans plans to repeal the Affordable Care Act will significantly affect healthcare M & A in the near term. Reforms may be delayed over time and implemented in phases or may be implemented more quickly.
- Momentum may slow for the adoption of new payment models. The new administration may alter or delay initiatives for bundled payments and outcome-based payments.
- The Trump campaign did not release an antitrust policy. However, the campaign's focus on increasing competition among insurance companies in order to reduce consumer premiums indicates that the new administration may continue the close scrutiny of consolidation among large insurers that has characterized the Obama administration.

"Our clients are faced with a host of complex and challenging decisions in a transition period. Just a few include how to protect against cybersecurity threats; how and whether to incorporate health insurance with actual healthcare delivery; and how to develop plans and address reimbursement models as the rules of the road change. 2017 will no doubt be a challenging year, with fundamental long-term decisions having to be made in a post-election evolving healthcare market."

- Phillip Street, Partner, King & Spalding

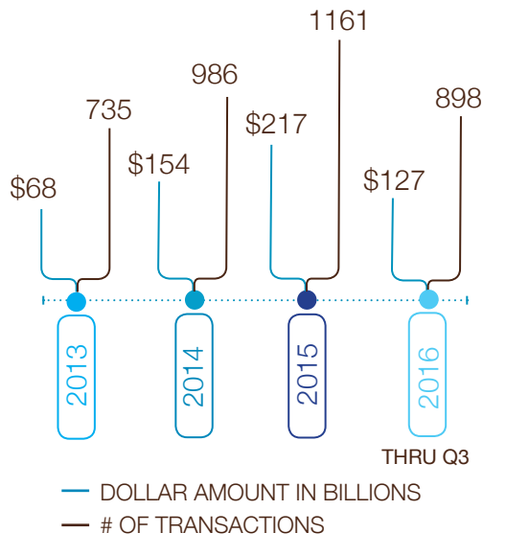
"Healthcare providers and investors in the healthcare industry have great opportunities, but the regulatory and reimbursement environment can be challenging. The shift to value-based pay, coupled with increasing regulatory complexity and enforcement generally, are creating a "perfect storm" for many providers. Small and middle market providers are seeing a particularly large impact, as they may lack the scale and expertise to respond to the changes. We are seeing significant vertical and horizontal consolidation across a number of provider sectors."

- Thomas Hawk, Partner, King & Spalding

Sector Focus

- The consolidation trend in the acute care sector is continuing, particularly in the southern United States where the acute care sector is currently more fragmented. This trend is driven by both private equity-backed firms and established regional not-for-profit health systems.
- Private equity and other financial institutions have devoted significant resources to post-acute providers, driving deal activity in the home health, hospice and senior living space, as well as physician and other ancillary health services such as behavioral health and dental and veterinary service organizations.
- Providers have focused on creating new care delivery models and adjusting existing models like Accountable Care Organizations to meet new care needs.
- There has also been significant deal activity in the healthcare IT sector.
- We expect increases in interest rates will put increased pressure on providers in capital-intensive areas such as hospitals, as well as nonprofits with limited access to capital.

Healthcare M&A Volume by Quarter



Valuations

- Deal value multiples continue to be elevated in certain sectors.
- Margins in the acute care sector are under pressure and leverage is high, leading some systems to use innovative consideration methods to get deals done (e.g., out year capital commitments).

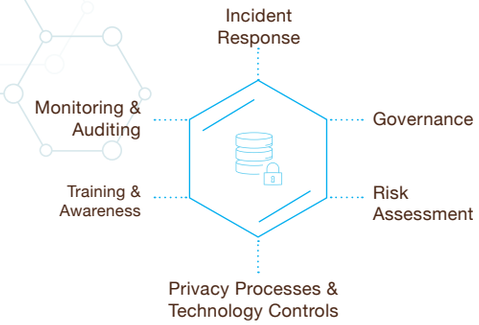
Deal Models

- Most providers pursue full integration models, with hospitals being a notable exception.
- Hospitals often explore different structures with varying levels of integration (e.g., management agreements, collaboration agreements, virtual mergers, joint operating companies and affiliations of different types).
- Physician, dental and veterinary service organizations (also known as practice management companies) may utilize so-called captive PC models to comply with state law restrictions on ownership of entities delivering professional services. ♦

Data Privacy and Security: HIPAA and Beyond

Threat Actors/Assets at Risk

Privacy/Security Governance & Infrastructure



Healthcare Attracts Cyber Threats

Cybercriminals find medical data more valuable than financial information alone, which is why it sells for 10 times more on the black market. There also is a perception that the health industry has fallen behind other industries in cybersecurity investment despite the health industry's focus on health information privacy and security from day one. And, in healthcare, cyber-attacks threaten more than business continuity and the bottom line – they can threaten lives. Cybercriminals are continuously seeking the optimal combination of low risk/effort and high reward, and the health industry increasingly is attracting their unwanted interest.

Healthcare Information Connectivity – Expect More, Not Less

Unlike industries that may have the luxury of being able to isolate and lock down their sensitive data, the inescapable imperative in healthcare is the need to connect data more and more. Clinical integration, innovative payment approaches and outcomes improvement all demand it. The connectivity is not only between healthcare providers, but is also with patients, with increasing linkage using mobile devices. These trends are unavoidable, and although they will make healthcare more accessible, transparent and efficient, they also will increase the cyber threat profile to a corresponding degree.

"No organization should be content waiting to develop an appropriate cybersecurity risk profile. If a full assessment and update cannot be accomplished in the immediate term, then take steps in the right direction, such as performing or updating targeted risk assessments and developing an incident response plan, and then start executing the plan in prioritized phases consistent with the highest-risk threats and vulnerabilities, as well as staffing and budget constraints."
- Phyllis Sumner, Partner, King & Spalding

"While Stark-based government enforcement actions routinely result in multimillion-dollar settlements, regulatory sanctions under HIPAA have been less severe. However, the settlement landscape has begun to change dramatically, with the dollar value of HIPAA settlements in 2016 exceeding the value of the preceding four years combined."
- Rob Keenan, Partner, King & Spalding

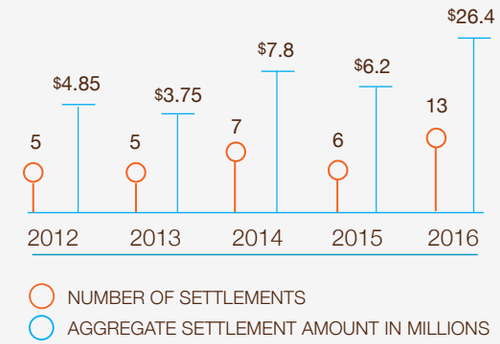
Regulatory Enforcement Is Catching Up With Other Sanctioning Regimes

The increasing frequency and magnitude of settlements that we are now seeing, and the expansion of government audit programs, will drive more investment in health industry privacy and security compliance infrastructure.

Proactive, Integrated Risk Management Will Prove Its Worth

HIPAA compliance is not enough to meet the coming cyber challenges. In fact, cybersecurity thought leaders believe that HIPAA regulation has impeded cyber readiness rather than promoted it, because HIPAA-regulated entities may be tempted to stop once all the boxes are checked. Threat assessment and response needs to be proactive, enterprise-wide and ongoing. Governance, IT, audit, compliance, training and incident response responsibilities must be mapped out and woven together.

HHS Office for Civil Rights Settlements



Third-Party Vendor Management Programs Are Evolving

Historically, third-party risk management was generally limited to getting third parties to sign business associate agreements. As enforcement expands to third parties, more health industry businesses are recognizing the importance of comprehensive third-party risk management programs, implemented early, with key functional components that apply throughout the life cycle of third-party relationships.

Implement Prioritized Strategies to Mitigate Risk

Health industry organizations are encouraged to:

- Ensure that governance and functional departments are integrated and working toward the same information privacy and security goals
- Conduct security risk assessments to identify key vulnerabilities and threats, and implement responsive measures
- Map compliance actions to applicable legal requirements, and document them
- Procure or update cyber insurance coverage
- Document and rehearse emergency response plans
- Conduct thorough diligence of third parties and acquisition targets
- Plan and budget for ongoing assessment and improvement – not "one and done" ♦

If You Have to Do More With Less, Then You Need a Proactive Reimbursement Strategy

It's true. Providers are being told to do more with less in the modern reform environment. These are a few of the basic tenets of healthcare reform:

- Push care, whenever possible, to less expensive settings.
- Adopt bundled payment models to lower costs by managing care across pre- and post-acute settings.
- Eliminate fee-for-service payment and the overutilization it encourages.

Government-funded insurance – particularly Medicare – has been a trailblazer in promoting these reforms. Consider the following:

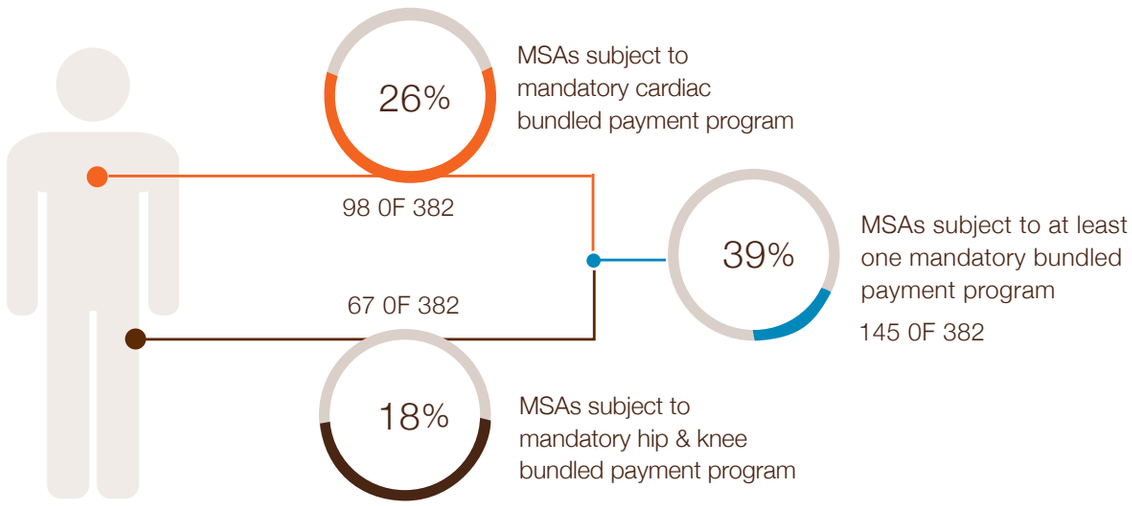
- In 2014, Centers for Medicare & Medicaid Services (CMS) adopted the Two Midnight Rule, which virtually eliminates Part A coverage for short hospital stays and pays for them at outpatient rates that are 30 percent of the inpatient rates. The aggregate number of inpatient Medicare stays has dropped from 9,860,000 in 2013 to 9,700,000 in 2015, a nearly 2% decrease that caused a steep decline in hospital revenue.
- In 2016, the Center for Medicare and Medicaid Innovation imposed mandatory bundled payment programs for some of the most common procedures in Medicare. Hospitals will be financially penalized if they do not realize a 3 percent savings to Medicare for costs incurred from admission through 90 days post-discharge. The programs have begun as pilots in a combined 145 Metropolitan Statistical Areas (MSAs), but CMS has made no secret of its desire to nationalize them. Whether the new administration rolls back these finalized programs remains to be seen.

"A majority of Medicare fee-for-service payments already have a link to quality or value. Our goal is to have 85% of all Medicare fee-for-service payments tied to quality or value by 2016, and 90% by 2018."
- Sylvia Burwell, New England Journal of Medicine (January 26, 2015)

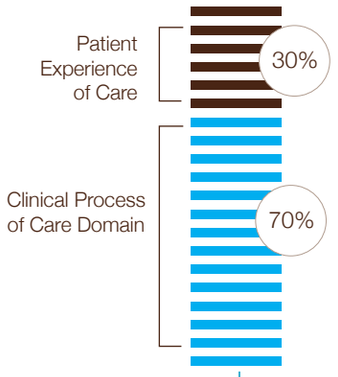
Financial Responsibility for Patient Outcomes

We will see the trend continue in which hospitals are held financially responsible for patient outcomes and Medicare spending. An increasing proportion of a hospital's Value-based Purchasing (VBP) Program score, for example, is contingent on Medicare spending and patient outcomes. In addition, many of the new measures added to the Inpatient Quality Reporting program, the precursors for the VBP measures program, revolve around outcomes and Medicare spending, including post-discharge spending, which is largley outside a hospital's control. >>

CMS's Bundled Payment Programs Are Now Mandatory in nearly 40% of the countries MSAs



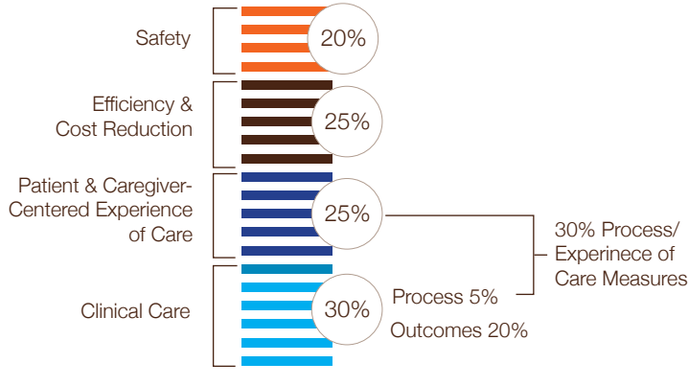
2013 VBP SCORE ALLOCATION



2013

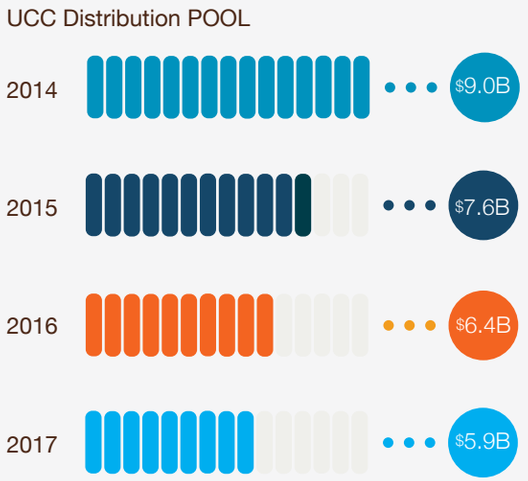
In 2013, when the VBP program was initiated, 70 percent of a hospital's score was based on simple "process" measures, while patient outcomes and Medicare spending, i.e., "efficiency," were not factors at all.

2017 VBP SCORE ALLOCATION



2017

In 2017, only 5 percent of a hospital's VBP score is based on process measures, while 70 percent is now attributable to patient safety, outcomes or "efficiency."



Drastic Cuts to Uncompensated Care Payments

Hospitals are the care providers of last resort for the uninsured, and they are left to subsidize the uninsured's healthcare bills. Healthcare reform promised expanded coverage through Medicaid and private insurance exchanges that would relieve hospitals of this burden.

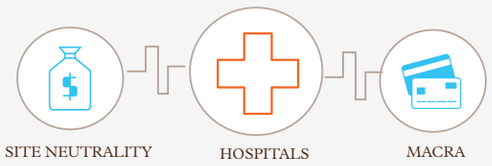
But coverage expansion has been a double-edged sword for hospitals. Hospitals continue to fund in part the subsidies that support private insurance exchanges through a series of Affordable Care Act "productivity" adjustments that impose downward adjustments on Medicare inpatient rates. And when it comes to uncompensated care, the Affordable Care Act gives with one hand but takes away with the other. For years, Medicare's disproportionate share hospital (DSH) program provided supplemental payments that offset the cost of uncompensated care. But the Affordable Care Act virtually eliminated the DSH program and replaced it with a program for uncompensated care that shrinks over time as the rate of private insurance coverage rises.

- In 2005, 71% of all hospitals received Medicare DSH payments. Total DSH payments were $9 billion. By 2013, that number had risen to 80% for a total of $12.5 billion.
- With the implementation of the Affordable Care Act, uncompensated care payments, meanwhile, have dropped from 2014 to 2017, falling by nearly one-third.

A Continued Focus on Alternative Payment Models Will Foster Competing Forces in Hospital-Physician Alignment

Though the flavor of healthcare reform may change with the times, the result is usually the same: increased physician-hospital integration. Payment reforms continue to demand more and more data reporting, for both hospitals and physicians. Physicians look to hospitals to carry those back office costs through employment or other affiliation arrangements. Hospitals, in turn, operate physician practices as provider-based clinics in order to support the overhead expenses associated with these administrative requirements.

This model has been upended by Congress and CMS's drive toward site-neutral payments – precisely when a new regime of physician reporting requirements under MACRA begins to take effect. How do physicians and hospitals navigate these increased administrative costs when the traditional route of provider-based status is less promising? The answer demands innovative alignment strategies, such as participation in Alternative Payment Models that reward high levels of integration without regard to care setting.



If You Have to Do More With Less, Then You Need a Proactive Reimbursement Strategy

Have You Thought About How to Survive the Payment Shifts and Tackle What's Coming Next?

The next four years are hard to predict, but it is likely that the trend of asking providers to do more with less will continue with the new administration. Providers will need a proactive reimbursement strategy – one that not only searches for existing opportunities for increased reimbursement, but also creates those opportunities. Here are some possible components for such a strategy.

- Be Vigilant – Adopt a plan to search for opportunities when they come along. In April 2016, CMS announced a radical shift in policy that made it easier for urban hospitals to adopt rural status and enjoy the corresponding reimbursement enhancements while maintaining urban wage status. Many hospitals missed the opportunity because they were not tied in to legal experts who understood this advantage.
- Advocate Your Case – If you have a dispute over reimbursement, do not simply accept the Medicare contractor's answer. When appropriate, seek a direct audience with CMS, which is often the same policy team that sets reimbursement policy. Our clients have successfully resolved dozens of reimbursement disputes worth millions of dollars without the need to file a formal appeal. Hospitals that do not take a similar approach can waste years and lots of money in an administrative appeal process with uncertain results.
- Think Boldly – While litigation is never a first choice, there is no question that selective litigation can create significant reimbursement opportunities. Working with us, our clients have created their opportunities by challenging:
  - The 0.2 percent Two Midnight Rate cut;
  - Medicare bad debt policies;
  - CMS denials of new residency program status;
  - CMS denials of provider-based status; and
  - CMS denials of critical access hospital status.
- Think About Single-Issue Lobbying Coalitions – Major hospital associations do not have the bandwidth to address every reimbursement issue that affects providers. They focus on the big picture and often play defense in beating back legislative proposals that will affect the industry as a whole, and rightly so. Many issues that affect subgroups of hospitals are left unaddressed. Providers can successfully team with each other through strategically configured single-issue lobbying coalitions to affect policy on those issues. These coalitions can work in a complementary way and support the trade associations. Our RAC Coalition clients, for example, have shaped the AFIRM Act, introduced in the Senate in 2016, to address Recovery Audit Contractor reform. We have also led coalitions that have played a part in advancing Stark Law reform and the introduction of legislation to correct an error in Medicare's graduate medical education reimbursement formula. ♦

"We encourage our clients to get out front on reimbursement changes. CMS sets Medicare reimbursement policy far in advance of the annual rule-making cycle. The time to advocate is the months before the proposed rules are released. Identify and target the small policy team within CMS that germinates ideas and filters them to the political leaders of CMS. If you limit yourself to commenting on the proposed rule, then you may be too late."
- Mark Polston, King & Spalding Healthcare Partner and former Deputy Associate General Counsel for Litigation, CMS Division, HHS Office of General Counsel, Washington D.C.

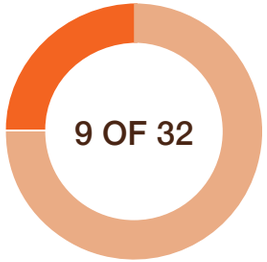
The Acceleration of Provider Risk Models in Managed Care Arrangements

The healthcare industry's shift away from fee-for-service reimbursement has put providers at the forefront of managing population health. In this new environment, the winning arrangements will be the ones that best incentivize providers to guarantee quality and promote efficiency.

- Steve Goff, Partner, King & Spalding

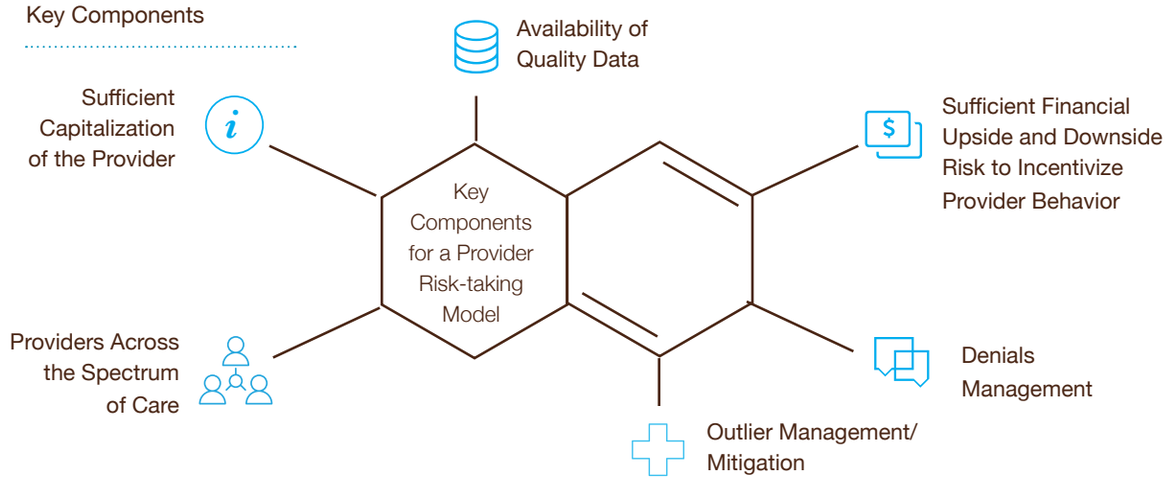
Despite significant uncertainty about what the healthcare landscape will look like under the Trump administration, it appears unlikely that the shift away from fee-for-service reimbursement methodologies is going to slow down. For many providers, this means that they must become better equipped to manage population health, and prepared to take on more of the financial risk for patient care. These arrangements are taking on many forms, including capitation and shared risk arrangements, as well as more direct risk taking such as the purchasing or sponsoring of health plans.

Some providers are better equipped to bear risk than others. Using but one example of a provider risk model, only nine of the original 32 Pioneer Accountable Care Organizations (ACOs) remain in operation. Those that remain in operation have seen mixed success with obtaining shared savings payments.



9 OF THE ORIGINAL 32 PIONEER ACOS REMAIN IN OPERATION

Compared with the traditional fee-for-service model that remains dominant in the healthcare industry, payor/provider convergence is still in its infancy, and, as a result, there is no such thing as a "template" agreement for payor and provider convergence. The agreement must be specifically tailored to the business needs of the parties and the particular needs of the patient population. That said, there are certain best practices that can be employed to give payors and providers a better chance at a successful transition from the fee-for-service model.



Sufficient Capitalization of the Provider | It is critical that payors and providers seek contractual provisions that give one or both parties early warning of impending insolvency. State regulations provide a good starting point for the information that the parties should exchange on a routine basis. The information can include such measures as cash on hand, ratio of cash to claims, net equity, incurred but not reported claims, and percentage of claims paid/not paid within regulatory time frames. Other metrics in addition to these basic financial metrics may also be necessary, depending on the nature of the arrangement.

Denials Management | Provider entities with financial risk for services must sometimes deny claims, triggering an appeal from the patient or rendering provider. The agreement with the payor should specify which entity, as between the provider entity and the payor, is going to process the second-level appeal. Providers may not want to cede to the payor the ability to overturn denials. This is particularly the case when the provider is financially responsible for the service in question.

Outlier Management/Mitigation | Many providers look to stop-loss insurance and other risk mitigation arrangements to hedge against unexpected costs.

Sufficient Financial Upside and Downside Risk to Incentivize Provider Behavior | Providers must have enough "skin in the game" to influence their behavior. There is no prevailing standard regarding how much risk is needed to change behaviors, so careful review of an organization's existing metrics must be used to set future goals.

Providers Across the Spectrum of Care | Providers in a risk arrangement need to be able to refer patients to other providers who are equally incentivized to provide efficient care. Otherwise, the provider will be financially responsible to pay providers who have little or no incentive to keep costs down.

Availability of Quality Data | Most risk arrangements use quality metrics as a "gate" to the provider receiving shared savings. If the provider meets the quality standards established by the contract, the provider will be entitled to a portion of the savings. The purpose of this gatekeeping function is to create strong incentives for the provider to focus on quality. Some risk arrangements also use quality metrics as a "ladder," where the degree to which the provider performs relative to certain quality measurements determines the amount of shared savings received by the provider. Contracts may have both gates and ladders, or one but not the other. The major challenge in negotiating gate and ladder provisions is agreeing on the metrics that will be used to measure quality, as there is no one set standard. ♦

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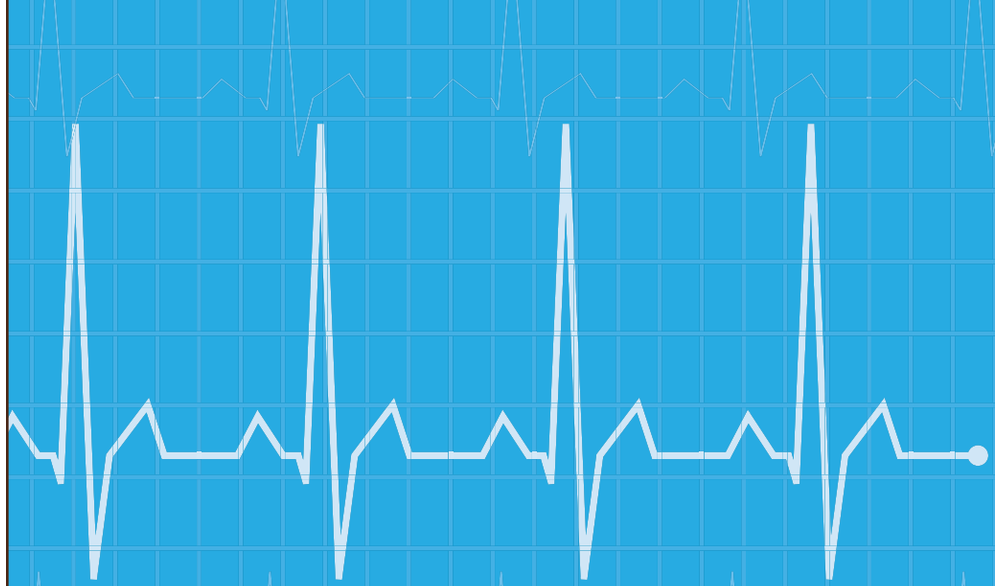

Our Healthcare Practice

King & Spalding represents organizations involved in the delivery of healthcare and in offering healthcare products across all facets of the legal issues they face. We serve the entire spectrum of healthcare institutional providers, practitioners, payors, educators, researchers, inventors, suppliers, investors and manufacturers across the country. Consistently ranked among the top firms nationally for healthcare law by Chambers USA, the practice comprises attorneys resident in Atlanta, Austin, Charlotte, Houston, New York, Sacramento, San Francisco, Silicon Valley and Washington, D.C.

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