KING & SPALDING

Our Insights Into Healthcare Industry Trends

2019

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2019

Almost nine years after the enactment of the Affordable Care Act, the country is still embroiled in uncertainty over its future as major judicial and congressional activity over the law looms in 2019.

For example, the Democratically controlled House took action on its first day in session to intervene in the Texas lawsuit that recently pronounced the unconstitutionality of the act.

We have endeavored in this edition of Our Insights into Healthcare Industry Trends to give our clients and friends our perspectives on a number of health law topics that are closely tied to political decisions made in Washington and that remain politically charged. These include:

» The future of the Affordable Care Act, as well as political activity impacting drug pricing and healthcare costs (pp. 1-3);

» Key government reimbursement trends and the impact of Medicaid changes, administrative priorities to reduce regulatory burdens and court rulings that create opportunities for providers (pp. 22-25);

» The enforcement priorities of the Department of Justice and HHS Office of Inspector General and how they require adaptation in compliance practices by providers across the country (pp. 4-8);

» Continued congressional focus on nonprofit tax exemption benefits (pp. 26-27);

» The antitrust enforcement climate in Washington and increased agency sensitivity to business combinations in the healthcare industry (pp. 20-21); and

» How government auditors are setting priorities when it comes to nontraditional healthcare providers like durable medical equipment suppliers, pharmacies, and labs (pp. 9-11).

We are also highlighting in this edition how the current health law environment impacts important business decisions our clients make. Topics that explore these issues include:

» The innovative transaction structures we are involved in on behalf of academic medical center clients (pp. 16-19);

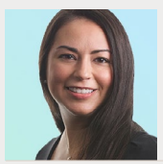
» Structuring healthcare acquisitions in the Middle East (pp. 12-15);

» U.S. transactional activity in healthcare (pp. 30-31); and

» The choices providers face when it comes to participation in tiered networks (pp. 28-29).

Whether it is on the government regulation and enforcement front, or in the broader climate of how health laws impact evolving healthcare delivery and strategic business structures and combinations, our healthcare practitioners are closely watching the developments in our industry. We are particularly attuned to how events in Washington are likely to create opportunities as well as to erect hurdles to our healthcare clients' strategies in the coming year. We hope you find the insights shared in this publication helpful as you plan for the success of your organization in 2019.

James Boswell
King & Spalding
Healthcare Practice
Team Leader,
Editor



Christina Ann McNamara
Counsel
Editor

The Midterm Elections and Their Implications for Healthcare Policy

Newly elected Speaker of the U.S. House of Representatives Nancy Pelosi (D-CA) observed of last November's midterm elections, "Healthcare was on the ballot, and healthcare won." Democrats successfully flipped control of the House by campaigning to maintain protections for individuals with preexisting conditions and to provide relief on healthcare affordability. A growing number of Democratic candidates not only defended the Patient Protection and Affordable Care Act (ACA) but supported an expansion to "Medicare for All." Republicans, many of whom touted their support for protecting individuals with preexisting conditions, were able to grow their Senate majority, defeating Democratic incumbents in states President Trump carried in 2016. And even several Republican-leaning states are expected to pursue Medicaid expansion following the 2018 elections.

And yet a major political time bomb went off on December 14, 2018, when United States District Judge Reed O'Connor of the Northern District of Texas issued a ruling declaring the ACA unconstitutional in its entirety. Although the ACA provisions will remain in place pending the appeal process, this ruling throws the U.S. healthcare system into flux.

While a divided government can offer the opportunity for bipartisan compromise, it is unclear that consensus extends beyond the widespread agreement on the need to protect coverage for individuals with preexisting conditions. Even here, the parties continue to disagree strongly on the method to do so. In the last Congress, bipartisan efforts to stabilize the individual insurance market failed. In this divided Congress, Republicans have no enthusiasm to further enshrine the ACA, and Democrats will resist efforts to undermine the law.

Indeed, on the first legislative day of the new Congress, the Democratic House voted to intervene in the Texas v. U.S. litigation. The ruling has already been appealed by a coalition of intervenor defendants, led by California Attorney General Xavier Becerra (D-CA), who served in the House during passage of the ACA.

House Democrats plan to hold hearings on the Texas court ruling, on efforts by the Trump administration to "sabotage" the ACA, and on proposals to expand health coverage. Over the next two years, the congressional Medicare for All Caucus and various 2020 Democratic presidential contenders will begin to flesh out the details of expansion beyond the ACA. These details were not necessarily critical for the 2018 midterm election campaigns. At the same time, Democrats do not want to risk repeating Republican missteps of having an effective healthcare rallying cry such as "repeal and replace" without implementing a successful legislative strategy. It remains to be »

seen which approach to expansion Democrats will ultimately support: a Medicare for All single national health insurance program, a new public plan option based on Medicare and offered to individuals and employers through the ACA marketplace, a "Medicare for More" buy-in option for individuals not yet eligible for Medicare to buy into the current program, a Medicaid buy-in option that states can elect to offer individuals through the ACA marketplace as a lower-cost option for individuals who do not qualify for traditional Medicaid but are priced out of other commercial options, or simply patching the holes the Trump administration has poked into the ACA. How the Democrats grapple with these competing approaches will set the terms of the debate for the 2020 campaign.

At the same time, the Trump administration will continue to implement Executive Order 13765, "Minimizing the Economic Burden of the Patient Protection Act Pending Repeal." The administration will continue to issue rules and guidance to reshape the law on topics such as association health plans and short-term health plans. While a Democratic House alone cannot halt these regulatory reforms through legislation or appropriations restrictions, they can slow the pace of reform by targeting congressional oversight to direct administration officials to testify about the decision-making process behind these actions.

Outside the fault lines of the ACA, the cost of healthcare will continue to be a primary focus of legislators and regulators.

Drug Pricing: Reducing the cost of prescription drugs is a top priority of President Trump and of congressional Democrats, leaving only the Senate Republican majority to oppose any legislative efforts. Last year, the Trump administration released its "American Patients First" blueprint to lower drug prices and has followed with a number of regulatory proposals. For instance, the administration sought comments on an "International Pricing Index" demonstration program, to link Medicare Part B payments to median prices in other countries. This proposal has drawn sharp opposition from branded pharmaceutical and biologics manufacturers, as well as hospitals and physicians. It remains to be seen whether Congress will push back once the details of the proposal are released.

"Outside of the fault lines of the ACA, the cost of healthcare will continue to be a primary focus of legislators and regulators."

Chris Kenny, ***Partner, King & Spalding***

While House Democrats have new oversight authority, congressional investigations of pharmaceutical manufacturers have traditionally been bipartisan and are expected to remain so. Members may continue to focus on specific areas, such as in the price of insulin and other drugs that have experienced very significant price increases. These investigations, which are expected to be active in the next year, frequently lay the foundation for future legislation and regulation. For instance, incoming Senate Finance Committee Chairman Charles Grassley (R-IA) and Ranking Member Ron Wyden (D-OR) introduced legislation last month to authorize the Department of Health and Human Services (HHS) to recoup rebates if drug manufacturers deliberately misclassify drugs into categories with lower Medicaid rebates, citing Mylan's settlement over its misclassification of the EpiPen as a generic, rather than a brand-name, drug.

Efforts to address drug pricing extend beyond authorizing importation and allowing government price negotiation. Chairman Grassley is expected to push bipartisan, bicameral legislation in the form of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, to deter prescription drug manufacturers from restricting sales of samples to potential generic competitors. Congress may also examine reforms to the Orphan Drug Act, a 35-year-old law designed to encourage the development of drugs for rare diseases. Congress worked on a bipartisan basis to pass the 21st Century Cures Act, to ensure that lifesaving therapies reach patients faster, and recognizes that some of these breakthrough therapies and treatments may put significant strains on federal and state budgets.

Healthcare Costs: Congress will seek to address healthcare costs to patients. The Senate Health, Education, Labor and Pensions Committee plans to continue work on affordability issues, particularly to address high out-of-pocket costs as well as surprise medical bills.

The administration will continue to address costs to federal health insurance programs through mandatory demonstration programs and development of value-based purchasing models. President Trump's original HHS secretary opposed the use of mandatory demonstration projects, while the current secretary is a supporter of them. Hospitals will face pressure on Medicare reimbursement rates – most notably to Part B drugs purchased through the 340B Drug Pricing Program and to certain off-campus outpatient department services. Congressional inquiries into hospital pricing and executive compensation, as well as additional action from CMS to require price disclosures online, are likely to continue. Hospitals also can expect questions about whether consolidation has led to an increase in prices; for example, leading candidates for the 2020 Democratic presidential nomination have been especially vocal about using antitrust laws to prevent additional consolidation.

Hospitals – particularly safety net providers – may have a more sympathetic audience with a Democratic House as they seek to maintain access to care. A coalition of safety net providers represented by urban Democrats and rural hospitals represented by Republicans may be effective in preventing additional rate cuts.

Hospitals should be proactive in defending their missions and the critical services they provide to patients and the community: providing care for the indigent and for insured patients whose cost-sharing obligations continue to increase; training the next generation of physicians and other practitioners at a time of profound demographic change; and deploying next-generation treatments and methods such as genomic medicine and telehealth.

Nearly a decade after enactment, the ACA and the role of government in healthcare continue to dominate policy debates in Washington. The debate leading up to the 2018 midterm elections and the results in many of those races confirm that federal policy on the availability and affordability of health insurance coverage will remain a congressional priority for the next two years. ◆

"Over the next two years, the congressional Medicare for All Caucus and various 2020 Democratic presidential contenders will begin to flesh out the details of expansion beyond the ACA. Democrats do not want to risk repeating Republican missteps of having an effective healthcare rallying cry such as 'repeal and replace' without implementing a successful legislative strategy."

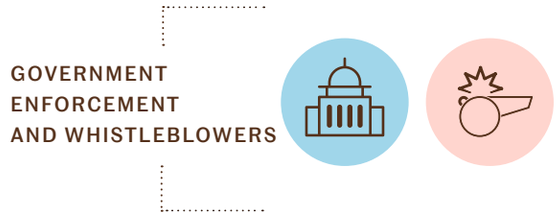
Allison Kassir, ***Government Relations Advisor, King & Spalding***

The Convergence of Enforcement and Compliance: Important Insights and Opportunities

While healthcare fraud enforcement escalates, critical authority recently issued from the Department of Justice (DOJ) and the HHS Office of Inspector General (OIG) that builds on prior authority and guidance provides important insight on enforcement approach priorities and opportunities for enhancing compliance and risk infrastructure.

"The government's emphasis on an organization's compliance profile and compliance program effectiveness continues to intensify. Consequently, an organization's approach to and investment in compliance will be a constant theme in government enforcement actions. Healthcare organizations should evaluate their compliance programs in light of these heightened compliance expectations to assess whether the compliance program meets current expectations and to identify ways to further enhance their programs."

Stephanie Johnson, ***Partner, King & Spalding***



THE LANDSCAPE

Government enforcement and whistleblower activity have continued unabated, with important developments to monitor, including the following:

- Sophisticated data analytics to identify targets of audits and investigations
- A growing number of industry segments at risk
- Use of more demanding and aggressive investigative tactics generally, with whistleblowers pursuing clandestine fact-gathering efforts
- Serial relators
- Experienced plaintiffs' counsel's active recruitment of whistleblowers
- Whistleblower representation by multiple law firms
- Private equity investment in whistleblower actions
- Increased prevalence of actions with partial or no government intervention
- Actions targeting individuals, including physicians, that are not limited to egregious conduct, but also include:
  - Individuals contributing to organizational conduct under investigation
  - Individual failures to adequately oversee or manage
- Resolutions and settlements that include specific individual remedies such as individual contributions to financial settlements and OIG exclusion actions. In FY 2017, OIG excluded 3,244 individuals and entities from participation in federal healthcare programs.

EXPANDING UNIVERSE OF WHISTLEBLOWERS

The universe of organizations evaluating organizational conduct is expanding quickly and dramatically:

- Lenders and investors are demanding comprehensive, detailed information on company risk in order to access financing.
- Insurers are pursuing more exacting information on compliance infrastructure, personnel and governance issues prior to renewing coverage policies.
- Shareholders and unions are pursuing losses and other remediation attributable to regulatory noncompliance.
- Investigative journalists are fixated on the healthcare industry and have influenced federal, state and other enforcement efforts.
- Shrewd business partners and potential partners are requiring more comprehensive diligence as reputational risk is paramount in today's environment.
- Talent recruitment similarly reveals that top performers seek stable organizations that value their reputation.

DOJ Assistant Attorney General Brian Benczkowski announced in October 2018 that when investigating and prosecuting all corporate cases across multiple industries, DOJ will:

- Consistently demand a "deep look into the sufficiency and proper functioning of the subject company's compliance program … with an analysis that includes the state of the program at the time of the alleged conduct and at the time of any proposed resolution."
- Invest in compliance in agency hiring practices and in efforts to pair trial attorneys with attorneys who have experience "developing and testing compliance programs."

These developments reflect a renewed and purposeful commitment by DOJ to prioritize compliance program effectiveness in the context of prosecutorial decisions. »

In September 2018, OIG announced that it would be providing additional online resources on the *Fraud Risk Indicator* and closed corporate integrity Agreements. These resources are intended to provide additional transparency into how OIG evaluates organizations on the risk spectrum.

The regulatory environment further complicates the landscape, based on numerous sources of regulatory risk that are often governed by fluid administrative standards and significantly enhanced coordination among government and private-sector stakeholders.

SIGNIFICANT RECENT COMPLIANCE AND ENFORCEMENT AUTHORITY

Both DOJ and OIG continue to issue important authority reflecting a new era of heightened compliance expectations, Compliance 2.0.

This authority includes:

- DOJ's October 2018 guidance, *Selection of Monitors in Criminal Division Matters*
- OIG's September 2018 announcement of additional online resources regarding the *Fraud Risk Indicator* and closed corporate integrity agreements
- DOJ's November 2017 guidance, *Revised Foreign Corrupt Practices Act Corporate Enforcement Policy*
- OIG's March 2017 guidance, *Measuring Compliance Program Effectiveness: A Resource Guide*
- DOJ's February 2017 guidance, *Evaluation of Corporate Compliance Programs (Guidance to Federal Prosecutors)*

Essential insights gleaned from this authority include:

- Never before has an organization's compliance and risk profile been as important to the enforcement community as it is now.
- The DOJ and OIG are aligned in their heightened compliance expectations and the compliance infrastructure they require.
- Organizations are expected to effectively prove the sophistication of their programs based on detailed authority issued by DOJ and OIG.
- Government investigations will focus on compliance program operations, culture, continuous improvement and results:
  - Scrutiny extends far beyond the compliance department to executive leadership, management, governance, operations, legal, human resources, internal audit, finance and other key functions.
  - Scrutiny includes specific individual roles and accountability.

Infrastructural areas raised by DOJ and OIG include:

- Evaluation of compliance administration, including personnel and qualifications, resources, standing and influence within the organization
- Dedication of executive leadership and management to a shared commitment and promotion of values, culture and operational integration of compliance responsibility
- Analysis of incentives used or to be developed to promote desired conduct and compliance leadership

"Now that the CMS final Medicare regulations addressing the 60-day overpayment reporting and refunding requirements have been in place for almost three years, the number of government investigations and whistleblower actions for reverse false claims under this theory of retention of overpayment liability is likely to increase. The time is now for providers to assess their overpayment refund controls to ensure that credible information of potential overpayments from both internal and external sources is analyzed promptly and any identified overpayments are timely reported and refunded."

Michael Paulhus, *Partner, King & Spalding*

- Governing body's composition, orientation and access to necessary information for effective oversight responsibilities, including areas of heightened risk
- Adequacy of organizational risk assessment and mitigation programs with focus on organizations' efforts to identify, prioritize and address potential risk, particularly new risk as companies grow and engage in healthcare transformation
- Development of numerous effective internal controls addressing:
  - Identification of areas needing heightened approvals or authorizations
  - Internal investigations
  - Root cause analyses
  - Remediation, including voluntary disclosures, repayments, prospective enhancements and disciplinary measures
- Soundness of data and analytics platforms as data integrity permeates numerous other infrastructural priorities
- Commitment to continuous improvement at macro- and micro-levels based on external and internal information:
  - Program and control evaluation
  - Target audits and reviews
- Oversight and responsibility of third-party arrangements and related protocols:
  - Business alignments and joint ventures
  - Vendors
  - Outsourced managers

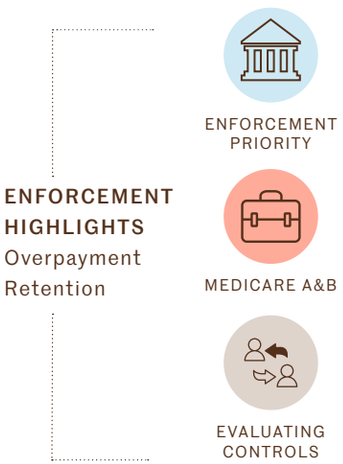
"A company that properly manages its risks through a robust and appropriate compliance function – one that grows along with the rest of the company – will remain ahead of the curve."

ROD ROSENSTEIN
Deputy Attorney General (May 21, 2018)

ENFORCEMENT HIGHLIGHTS

Overpayment Retention

- The improper retention of overpayments is an enforcement priority, and we expect the enforcement activity in this corridor to continue to increase now that the CMS Medicare Parts A and B Final Rule has been final for several years.
- There are many subjective aspects of the CMS Medicare Parts A and B Final Rule that make this an area ripe for enforcement and whistleblower activity. Indeed, we are already seeing overpayment retention enforcement.
- Organizations should consider proactively evaluating their controls regarding overpayment identification and the associated reporting and refunding requirements, in light of the heightened enforcement scrutiny that is anticipated. »



"Recent developments provide organizations with a unique opportunity to strategically invest in proactive compliance efforts that align with elevated enforcement expectations. Significant DOJ and OIG efforts signal that organizations are seeking greater predictability and recognition for proactive compliance initiatives. Accordingly, successful compliance will be driven by ongoing efforts to identify and enhance controls and other activity in areas emphasized in recent regulatory and enforcement issuances. Conversely, superficial programs lacking robust activity and leadership support will not only fail to reduce organizational risk, but will also negatively position organizations (and possibly individuals) in the context of external scrutiny."

Sara Kay Wheeler, *Partner, King & Spalding*

Medicaid Managed Care

- Managed care has become the primary delivery system for Medicaid.
- There has been increasing criticism of the lack of Medicaid program integrity efforts to ferret out and prosecute fraud and abuse. For example, in July 2018, OIG issued a report addressing the weaknesses in the program integrity efforts for Medicaid managed care.
- Given that the primary delivery system for Medicaid is managed care, expectations are now being placed primarily on the managed care organizations (MCOs), which manage the care, and secondarily on traditional federal and state enforcement entities.
- We expect Medicaid managed care enforcement efforts to continue to increase, and healthcare organizations are likely to experience more involvement by the MCOs as the MCOs attempt to respond to pressure to combat perceived fraud and abuse.

Outsourcing and Third-Party Management

- In the current, heightened compliance environment, it is increasingly important that healthcare providers be aware of the potential risks posed by third parties they contract with or engage and ensure there is appropriate oversight.
- Healthcare providers can help mitigate compliance risks in this area by enhancing oversight of the activities of third-party vendors by developing enterprise-wide controls for third-party oversight, which include independent review of third-party performance, such as evaluating compliance with contractual obligations.
- Providers may also consider performing additional due diligence to ensure the organization has sufficient compliance controls prior to entering into an arrangement with a third-party vendor or business partner. ◆

Rise of Nontraditional Providers in an Era Targeting More Convenient Healthcare Delivery Models

The delivery of healthcare is evolving into a model focused on patient convenience and reduction of overhead costs, which offers the option for patient care without face-to-face encounters with providers.

These providers, which we refer to in this section as "nontraditional providers," include durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers; pharmacies; home health agencies; laboratories; diagnostic testing facilities; and telehealth providers. As part of this trend, healthcare consumers are becoming more reliant on healthcare services provided in the home, and demand for such services is increasing. Patients increasingly receive their drugs, medical devices and supplies, and diagnostic services through mail-order, electronic or transtelephonic means. They more frequently seek out medical consultations via telephone, computer and hand-held device.

"We are seeing an uptick in investment in healthcare providers who offer models of convenience, such as those more commonly furnished by DMEPOS suppliers and mail-order pharmacies. While these models will continue to pave the future of healthcare delivery, we have also seen heightened scrutiny from both state and federal regulators as agencies try to keep pace with enforcement vehicles compatible with the growing demand for change."

Juliet M. McBride, *Partner, King & Spalding*

NONTRADITIONAL PROVIDERS

- DMEPOS
- HOME HEALTH AGENCIES
- LABORATORIES
- PHARMACIES
- DIAGNOSTIC TESTING FACILITIES
- TELEHEALTH PROVIDERS

The convenience of the new models, however, brings with it unique regulatory risks, overlapping federal and state requirements, reimbursement challenges, and heightened government scrutiny. These challenges require nontraditional providers to tackle issues that are unique to their businesses and not well-developed within the direct-to-home healthcare services space. »

MEDICARE AND MEDICAID AUDITS AND APPEALS

With the combination of increased Medicare (and Medicaid) audits and denials based on technical subregulatory guidance, a single audit can result in a nontraditional provider being put out of business before its denied claims can be adjudicated by a neutral tribunal. Other common challenges with audits and appeals include the growing use of extrapolation techniques based on sample reviews and the continued backlogs and delays in the appeals process.

The current environment demands that providers critically assess ways to keep pace with and stay ahead of rapidly changing and often inconsistent reimbursement guidance issued at the local and national levels. Nontraditional providers, such as mail-order and telehealth suppliers, can help to influence policy developments by staying engaged with CMS leadership and advocating for advancements relevant in the direct-to-home healthcare services space.

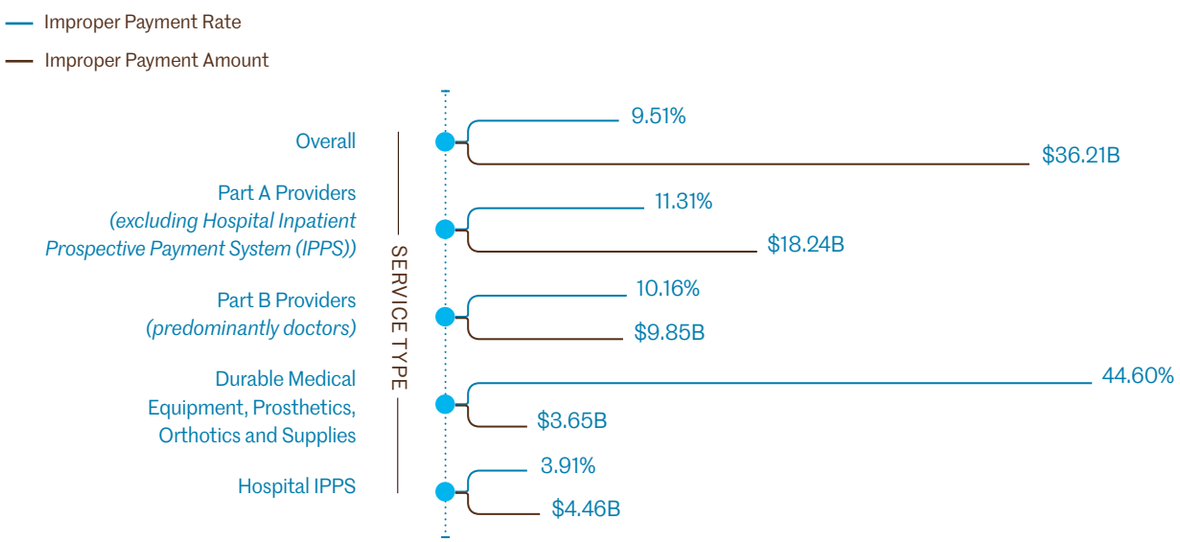
PAYMENT CHALLENGES

Nontraditional providers are often reimbursed under Medicare Part B and have fallen victim to:

- Shrinking reimbursement rates (especially as they relate to the Medicare DMEPOS competitive bidding program);
- Expanding interpretations of supplier enrollment requirements and more frequent revocations of the same;
- Questionable agency efforts to lower or further manage Medicare payment, often resulting in increased claims reviews and denials;
- Competitive bid processes; and
- Demands for documentation from prescribing physicians that often is not maintained or willingly furnished by such practitioners or that, even when furnished, may be determined to be insufficient support for payment.

FIGURE 1: IMPROPER PAYMENT RATE AND PROJECTED IMPROPER PAYMENT AMOUNT BY CLAIM TYPE FOR FY 2017

Reporting Period: July 1, 2015–June 30, 2016.



Source: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/index.html

According to CMS data, the Medicare Fee-for-Service improper payment rate calculated through the Comprehensive Error Rate Testing program for the fiscal year (FY) 2017 Medicare FFS program is 9.51 percent, representing $36.21 billion in improper payments (see Figure 1).

Based on the evidence published by CMS, nearly half of all DMEPOS claims are labeled "improper," which puts these suppliers in the position of defending the bulk of their claims billed to the Medicare program.

Many providers have answered these challenges in a similar way — by entering into managed care arrangements and relying less on government payer models. It comes as no surprise, however, that managed care presents a different territory and negotiation strategy from traditional Medicare fee-for-service or physician fee schedule models. Too often, nontraditional providers are limited from entering into certain managed care arrangements, as many of those arrangements involve limited networks. Further, pharmacy benefit managers and commercial health plans often have the ability to unilaterally determine payment requirements (especially for out-of-network suppliers) and to exclude suppliers from participation in their networks. In addition, commercial health plans are increasingly adopting Medicare's techniques of claims audits, extrapolations and overpayment demands. Thus, managed care can sometimes lack the predictability expected from Medicare and other federal healthcare programs.

"Given that the laws were not designed to address newer, cutting-edge forms of healthcare service and delivery models, many of our clients expanding into these novel areas are faced with increasing payment audits and challenges on a routine basis. We are seeing certain providers succeed in this environment by engaging more frequently with regulators at the onset of proposed changes to business and healthcare delivery models."

Seth H. Lundy, *Partner, King & Spalding*

OPTIONS FOR NONTRADITIONAL PROVIDERS

To effectively navigate in an environment that demands more and more services but puts nontraditional providers at increasing risk of not being paid for those services, providers require expert support and guidance to, among other things:

- Effectively track new and emerging federal legislation, regulation and guidance;
- Challenge new developments that unfairly prejudice nontraditional providers by lobbying agencies and Congress, submitting strong public comments, and bringing litigation against government agencies;
- Better assess their own processes for identifiable risks and ways to mitigate challenges from payers;
- Address questions and risks before they are potentially replicated over large numbers of claims and/or longer periods of time, exposing the provider to significant financial risk;
- Appeal errant denials and become more effective with the challenges offered in such appeals; and
- Join in coalitions of similarly situated providers (and other stakeholders) to expand their influence in a cost-effective manner. ◆

Practical Considerations for Structuring Healthcare Acquisitions in the GCC

The healthcare sector in the Cooperation Council for the Arab States of the Gulf (GCC) has shown substantial M&A activity. The level of activity led to a spike in the valuation of healthcare targets, particularly in specialist areas such as cosmetic and plastic surgery, rehabilitation, diabetes, and long-term healthcare.

The level of M&A activity has varied considerably across the six countries of the GCC (see Figure 1). Saudi Arabia and the United Arab Emirates (UAE) have been the most active markets. In Saudi Arabia, we are seeing growing interest from investors in greenfield and brownfield general hospitals and medical clinics, including dialysis, home healthcare, rehabilitation and in vitro fertilization (IVF) clinics. Within the UAE, the focus has been on cosmetic and plastic surgery centers (in Dubai), long-term care and rehabilitation facilities (in Abu Dhabi), and specialized clinics (in Al Ain). Table 1 sets out a list of major healthcare M&A deals that have closed in the GCC over recent years.

Privatization in the healthcare sector in Saudi Arabia has also triggered M&A activity. This is likely to continue and may spill over into neighboring GCC states, such as Kuwait. The number of public hospitals still far exceeds that of private hospitals (75 percent to 25 percent, respectively), but this may change substantially over the next few years.

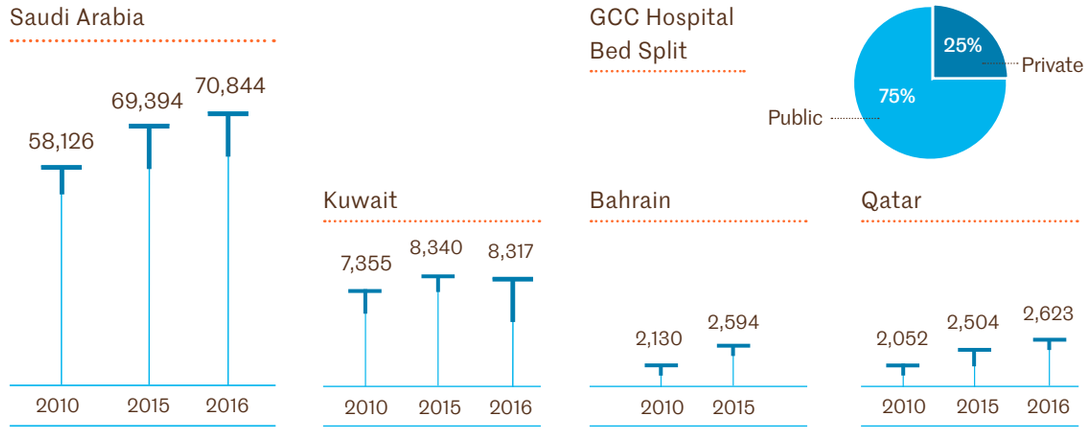
Given the growing trend in healthcare transactions across the GCC, this article aims to provide an overview of some of the key practical points to consider when structuring these transactions.

FIGURE 1: THE LEVEL OF M&A ACTIVITY ACROSS THE GCC

RESTRICTIONS ON FOREIGN OWNERSHIP

Restrictions on foreign ownership exist in various countries in the GCC, including in Saudi Arabia, the UAE (except within certain free zones, where up to 100 percent foreign ownership in healthcare businesses operating in the zone is permitted) and Oman. Each of these jurisdictions requires local contribution in the ownership of a healthcare facility. Nonlocal investors often enter into "risky" ownership structures with local owners to circumvent restrictions on foreign ownership. Under such ownership structures, a local owner holds its ownership interest in the entity as a nominee for the foreign investor.

FIGURE 2: GCC HOSPITAL BEDS



COUNTRY	NUMBER OF HOSPITALS	YEAR
Saudi Arabia	470	2016
UAE	126	2015
Qatar	14	2016
Oman	74	2016
Bahrain	25	2015
Kuwait	33	2016

However, local courts of certain GCC countries have invalidated ownership structures on the basis that such schemes are in breach of local anti-fronting laws, which generally prohibit foreigners from conducting any economic or professional activity that violates local laws (including the foreign ownership restriction discussed above). With certain GCC countries moving to liberalize restrictions on foreign investments, such as the UAE and Saudi Arabia, it is expected that such schemes will be brought under further scrutiny and challenges in the future. We note that in October 2018, the Saudi Arabian General Investment Authority announced that foreigners can now, for the first time, invest in medical clinics and hospitals with fewer than 100 beds (previously foreigners could invest only in hospitals with more than 100 beds).

Given the above issues, the first step to any healthcare acquisition should be to determine an appropriate, enforceable and tax-efficient ownership structure to mitigate the effects of a particular foreign ownership. Such structures include offshore company and investment fund-based structures in Saudi Arabia, the Dubai International Financial Centre and Abu Dhabi Global Market and financing-based structures using profit participation »

TABLE 1: MAJOR HEALTHCARE M&A DEALS IN THE GCC

ACQUIRER	ACQUIRER'S COUNTRY	TARGET	TARGET'S COUNTRY	YEAR	CONSIDERATION *(US$ Million)*	PERCENT SOUGHT *(%)*
NMC Health Plc	UAE	Al Zahra Private Hospital Sharjah	UAE	2016	560	100%
NMC Health Plc	UAE	Fakih IVF Group	UAE	2018	205	49%
NMC Health Plc	UAE	Cosmesurge*	UAE	2018	170	70%
VPS Healthcare	UAE	3 hospitals of Rockland Hospitals Ltd.	India	2016	149	100%
Amanat Holdings PJSC	UAE	International Medical Center	Saudi Arabia	2017	97	13.2%
Kuwait Finance House KSCP	Kuwait	Al Salam International Hospital Co.	Kuwait	2017	65	20.9%
NMC Health Plc	UAE	Al Rashid Hospital	Saudi Arabia	2017	40	100%
NMC Health Plc	UAE	Al Qadhi Hospital	Saudi Arabia	2017		60%
NMC Health Plc	UAE	Al Salam Medical Group*	Saudi Arabia	2018	37	80%
Saudi Pharmaceutical Industries & Medical Appliances Corp. SJSC	Saudi Arabia	Al Qassim Medical Services Co.	Saudi Arabia	2016	36	27.3%
Investor Group	NA	NMC Health Plc	UAE	2017	30	4.9%
NMC Health Plc	UAE	As Salama Hospital	Saudi Arabia	2016	28	70%
Saudi Pharmaceutical Industries & Medical Appliances Corp. SJSC	Saudi Arabia	Al Qassim Medical Services Co.	Saudi Arabia	2016	18	13.2%
NMC Health Plc	UAE	As Salama Hospital	Saudi Arabia	2018	13	30%
Al Hammadi Co. for Development & Investment	Saudi Arabia	Medical Support Services Co.*	Saudi Arabia	2017	13	100%
PT Kimia Farma (Persero) Tbk	Indonesia	Dawaa Medical Ltd. Co.	Saudi Arabia	2018	10	60%
Kaya Middle East DMCC	UAE	Minal Medical Centre, Minal Specialized Clinic Dermatology	UAE	2016	6	75%
Undisclosed Acquirer	NA	Asnan Tower*	Kuwait	2018	1	N/A
Mediclinic Middle East Management Services FZ LLC	UAE	Al Madar Medical Center LLC	UAE	2016	N/A	100%
		Aspetar Medical Center LLC	Qatar			
		Manchester Medical Clinic LLC	UK			
Emirates Hospital LLC	UAE	Mobile Doctors 24-7	UAE	2017	N/A	60%
Aster DM Healthcare LLC	UAE	Harley Street Medical Centre	UAE	2016	N/A	60%

Source: Thomson Reuters Eikon (as cited in the report on GCC Healthcare Industry, Alpen Capital, March 26, 2018).
*Deals pending completion as of March 16, 2018.

financing instruments and even debt capital market instruments such as bonds and sukuks. Some of these structures have been used widely across the GCC, and some are novel and will see substantial growth over the next few years. The ultimate acquisition structure will vary depending on commercial drivers and the costs required to implement and maintain them. Such structures have also been useful in obtaining financing from parties outside the region and in providing robust English law-based security packages for such financing.

CONSIDERATIONS RELATING TO THE PURCHASE PRICE

Sellers often refuse to guarantee the future performance of a business after it has been acquired by a purchaser. With targets being prone to factors that can bring down their valuations and returns, purchasers often lean toward deferring a portion of the purchase price. Such a deferred portion is often paid to the seller only after certain financial targets are achieved.

Other mechanisms by which the purchaser can protect the purchase price include adopting a purchase price adjustment mechanism based on working capital and debt targets, repeating warranties on the past performance of the targets at closing, and requesting indemnity coverage for known potential liabilities that are likely to arise after closing.

"In October 2018, the Saudi Arabian General Investment Authority announced that foreigners can now, for the first time, invest in medical clinics and hospitals with fewer than 100 beds. As a result of this expansion of foreign ownership rules, we expect to see a significant uptick in the level of foreign investment in the healthcare sector in Saudi Arabia and are already receiving inquiries from UK- and US-based hospital groups."

Nabil A. Issa, ***Partner, King & Spalding***

"With a growing population and undersupply in specialist facilities in the Cooperation Council for the Arab states of the Gulf, we are seeing investors and healthcare providers moving toward investment in specialty facilities, including in the areas of cosmetic and plastic surgery, optics, rehabilitation, diabetes, and long-term healthcare."

Simon Rahimzada, ***Partner, King & Spalding***

A foreign purchaser should seek to protect its interests by entering into an agreement with the healthcare license owner to regulate their relationship with respect to the healthcare license. For instance, the agreement should stipulate that the healthcare license owner will fully cooperate with the purchaser to renew the healthcare license and will refrain from taking any action that could cause the license to lapse. It may be possible to have such an agreement trigger liquidated damages to improve enforceability in the event the GCC party does not comply with the requirement to maintain and renew the relevant healthcare license.

OUTLOOK

The outlook for the health industry in the GCC remains optimistic, which is likely to drive further M&A activity in the region. However, there are a number of potential issues arising out of M&A transactions in the GCC that all potential purchasers will need to consider carefully with their professional advisors to ensure a smooth and timely transaction. ◆

Academic Medical Centers and Innovative Transaction Structures

AMC TRANSACTION TRENDS

Academic medical centers (AMCs) are now facing increasing market demands to grow, innovate and expand service line offerings. When affiliating with partners as part of their growth strategies, AMCs often must pursue specific transaction structures due to constraints imposed by healthcare laws and other regulations. These alternative transaction structures can supplement or even replace mergers or acquisitions as a mechanism for growth and expansion.

Factors Driving Growth, Innovation and Expansion

In the current healthcare regulatory climate, where government reimbursement is declining, expenses are rising, and regulations are changing or threatening to change, even the near future can be unpredictable. AMCs are facing increased financial pressure to grow within and outside their current markets, to find new and innovative ways to provide high-quality care across the healthcare continuum, and to seek additional sources of revenue. AMCs are responding to these pressures by partnering in creative ways with other health systems and hospitals.

Alternative Transaction Structures to Accomplish Goals

Due to potential limitations on mergers with and acquisitions of other providers for antitrust and other reasons, AMCs are increasingly entering into strategic affiliations through alternative structures such as joint ventures, joint operating arrangements, collaborations, service line agreements and management arrangements. These alternative transaction structures may result in less comprehensive integration than standard mergers or acquisitions offer but can be more flexible in their duration and delineation of obligations, liabilities and rights among the parties. These structures still afford AMCs the ability to deliver cost savings by leveraging the economies of scale inherent in more traditional health system structures. They can also enable AMCs to focus on their areas of specialty (e.g., training physicians and providing high-quality healthcare services to their communities) rather than performing administrative tasks that are the specialty of a collaborating partner.

"Due to the unique composition of AMCs, AMC transactions are generally complex and require careful attention to ensure compliance with all applicable laws. In addition to traditional fraud and abuse, antitrust, and other healthcare regulations, many AMC transactions must also be structured to comply with state constitutions and statutes applicable to state agencies."

Adam Robison, ***Partner, King & Spalding***

Legal and Regulatory Constraints

Many AMCs are owned and operated by state agencies that operate within a robust regulatory framework. In the context of collaborative arrangements, this framework generally requires state agencies to have sufficient controls in place to ensure the ongoing achievement of their stated public purposes. But these requirements should not prevent state agencies from benefiting from opportunities for collaboration. Unlike traditional M&A transactions, alternative transaction structures can be tailored to satisfy agency-specific regulatory requirements and provide a level of control sufficient for each collaborating partner.

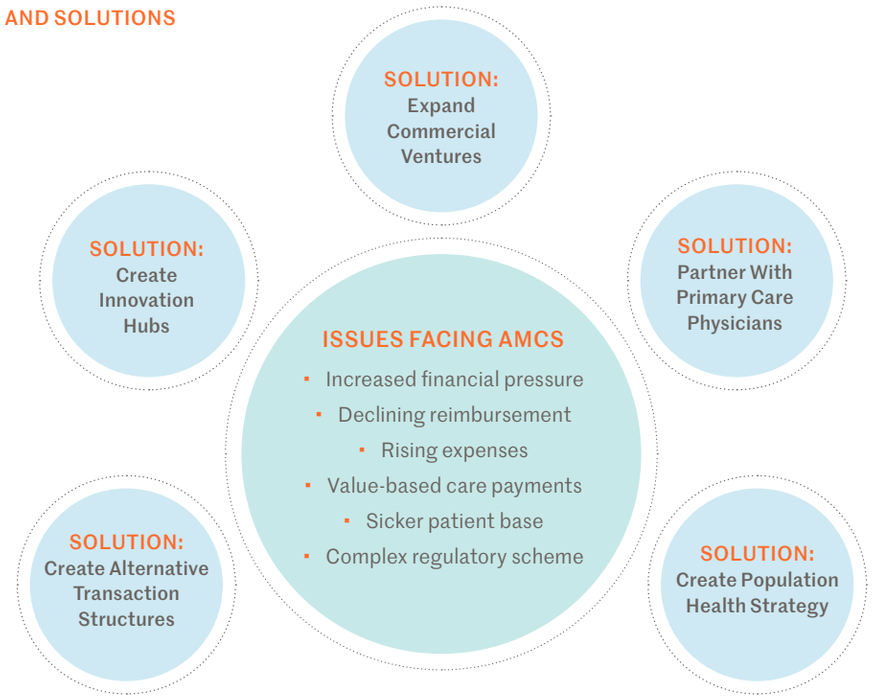
AMCS AS INDUSTRY LEADERS

In recent years, AMCs have evolved from being mere providers of healthcare services to becoming innovative industry leaders seeking to address the most pressing health issues of their communities, including through preventive measures.

Proactive Problem-Solvers

- Many AMCs are working with other hospitals and community partners to implement creative solutions to address community health issues, including the opioid epidemic, behavioral health, obesity and homelessness, and expanding direct-to-employer offerings.
- AMCs are also collaborating with others to expand access to clinical programs, including access to clinical trials across service lines. They are partnering with other hospitals to expand training placements (for example, MDs, nurses, allied health professionals and graduate medical students) and to share education and research resources such as continuing medical education programs. »

AMC ISSUES AND SOLUTIONS



"AMCs will continue to innovate in 2019 as they evolve from being providers of healthcare services to creative industry leaders, including forming incubation hubs and entering into new business lines for alternative revenue sources beyond traditional patient care services."

Ranee Adipat, ***Counsel, King & Spalding***

- In addition, AMCs are entering into affiliations that allow the organizations to optimize back-office services and operations through joint procurement of material contracts and workforce management (for example, sharing workforce management tools, improving retention rates and coordinating recruiting efforts).

Innovators

- In June 2018, a Colorado-based AMC announced its plan to create an innovation hub in a first-of-its-kind center where experts from inside and outside the health system will work together to incubate new ideas and help transform healthcare delivery of the future, including supporting developments in artificial intelligence, big data analytics, clinical decision support, virtual health and wearables.
- A California-based AMC launched a center focused on health quality and innovation designed to promote, support and nurture innovations at its medical campuses and hospitals to transform the way Californians' health needs are addressed and to advance health in California and beyond. The center was launched in 2010 and has awarded more than 50 grants totaling $15 million, formed systemwide collaborations and developed partnerships to improve patient outcomes.

AMCS ALIGNING WITH PHYSICIANS

AMCs are also finding new strategies to align with primary care physicians and specialists to address population health needs in their communities, including entering into Medicare and commercial shared-savings programs and other risk-based contracts through accountable care organizations (ACOs), forming clinically integrated networks (CINs), and acquiring primary care practices and other physician organizations.

Population Health Evolution

- AMCs are uniquely positioned to manage populations as a result of their expertise in innovation, access to broad ranges of physician specialists and strong physician leadership. AMCs' tripartite mission of providing clinical services, educating the next generation of physicians and conducting research gives AMCs an advantage in influencing population health.
- To transition to a population health paradigm, however, AMCs have to overcome a number of obstacles inherent in their traditional structure. These obstacles include lack of an adequate primary care physician base, decentralized academic departments, continued focus on traditional fee-for-service payment models as opposed to risk- and value-based payment systems, and potential lack of alignment between physicians, hospitals and post-acute care providers.

Physician Practice Acquisitions, ACOs and CINs

- AMCs have responded to these population health implementation challenges in a variety of ways. For example, in acknowledgment that primary care physicians are the cornerstone of any successful population health strategy, some AMCs are acquiring physician practices, particularly primary care group practices.
- Another strategy AMCs have employed to affiliate with primary care physicians and to provide population health services is to form ACOs and/or CINs to participate in governmental and commercial shared savings programs. Despite challenges faced by AMCs in implementing such programs (e.g., governance structures that vary from required ACO governance, decentralized academic departments that lack clinical integration, tenure systems that focus largely on research and reputation instead of clinical excellence, and, in many cases, a lack of a primary care physician base), a number of AMCs now participate in the Medicare Shared Savings Program and other ACO programs and have had substantial success in achieving shared savings.

AMCS EXPANDING INTO OTHER COMMERCIAL VENTURES

As a means of generating additional sources of revenue, hospitals, health systems and AMCs are becoming more involved in ventures outside the traditional patient care realm, such as revenue cycle management, generic drug manufacturing, and device and drug development.

Revenue Cycle Management

- Health systems and AMCs are partnering with, developing or acquiring revenue cycle companies to simplify billing, improve collections and improve patient experiences.
- In 2015, an academic health system based in New Hampshire that serves a population of 1.9 million in New England partnered with a national health system's revenue cycle management subsidiary for revenue cycle management services, including patient access, coding and accounts receivable management, for hospital and physician services across the health system. The academic health system expanded the relationship in 2017 to include another 116-bed hospital affiliate.

Generic Drug Manufacturing

In January 2018, four health systems, in consultation with the U.S. Department of Veterans Affairs, announced the creation of a nonprofit generic drug company. The health systems, together with the VA, represent more than 450 hospitals around the U.S. In addition, 70 other hospital systems have since expressed interest in joining the venture. The new company intends to be an FDA-approved manufacturer and will either directly manufacture generic drugs or subcontract manufacturing to reputable contract manufacturing organizations. The goal is to provide patients an affordable alternative to products from generic drug companies. The company will also seek to stabilize the supply of essential generic medications administered in hospitals, many of which have fallen into chronic shortage.

Device Development

- In 2016, a Dallas-based state medical school joined a consortium of seven leading universities to develop new technologies to improve memory in people with traumatic brain injury, mild cognitive impairment, epilepsy and Alzheimer's disease. Specifically, the medical school is involved in a study with the goal of developing by the end of 2018 an implantable neural monitoring and stimulation system that would improve memory function.
- In early 2018, an Ohio-based medical school and large healthcare system developed a simple, swallowable balloon device used for early detection of cancer of the esophagus in order to prevent deaths from Barrett's esophagus. The device offers a minimally invasive, cost-effective alternative to endoscopy. ◆

Healthcare Remains an Enforcement Priority of the Antitrust Agencies in the Trump Administration

On November 30, 2018, the Department of Health and Human Services (Department), in conjunction with the Treasury Department, the Federal Trade Commission (FTC), and the Department of Labor, issued a report (Report) describing a number of concerns regarding competition in the healthcare industry.

The Report points to potential anticompetitive effects of mergers by competing hospitals and physician practices, noting that the reduction in competition tends to result in higher prices for patients. According to the Report, competition among hospitals and physician practices is typically highly localized, and therefore the elimination of even one competitor could potentially result in a highly concentrated market. The Report further notes that, in addition to higher prices for patients, consolidation may also allow healthcare providers to negotiate higher reimbursement rates from insurers, potentially leading to increased insurance costs for consumers.

"There is a bias in the FTC and the DOJ that provider consolidation does not benefit consumers. Being able to point to patient outcome and healthcare cost improvements that resulted from prior transactions will be critical in getting antitrust approvals for future strategic collaborations."

Jeffrey Spigel, ***Partner, King & Spalding***

The Report also identifies several barriers to entry created by state regulations, which tend to limit physicians' ability to provide certain types of care, operate in certain areas, or even enter the market at all. The Report points to the restrictions imposed by state licensing, reimbursement, and scope-of-practice regulations, which, if overbroad, may reduce the availability and quality of the care patients receive. In addition, the Report addresses the potential anticompetitive effects of state "certificate-of-need" (CON) laws on healthcare providers and finds that CON laws may increase the cost of market entry and impose significant regulatory hurdles on providers seeking to enter certain markets. The Report also examines the role of state "certificate-of-public advantage" (COPA) laws in protecting otherwise anticompetitive agreements between healthcare providers from antitrust scrutiny under the state action doctrine, even if their overall result is to lessen competition.

The concerns outlined in the Report are not new. Provider consolidation in particular has been the subject of a number of news articles and has been an enforcement priority of the FTC and Department of Justice, Antitrust Division (DOJ), for several years. In July 2018, FTC Chairman Joe Simons – who was appointed by President Trump – testified before the U.S. House Energy and Commerce Subcommittee on

"The DOJ and the FTC continue to focus on the healthcare industry and closely scrutinize transactions, networks and managed care contracting."

John Carroll, ***Partner, King & Spalding***

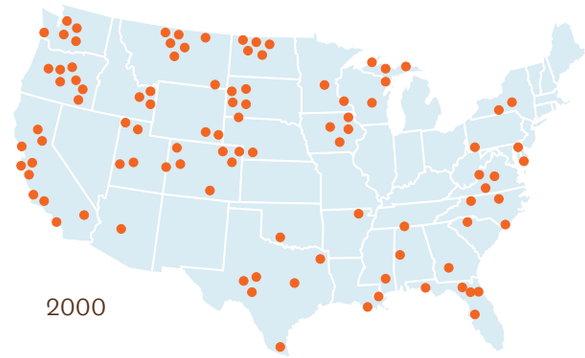
Digital Commerce and Consumer Protection and identified the healthcare industry as one of the "sectors of the economy that directly affect consumers and their pocketbooks."

The agencies have not been all talk. In fact, they have brought a number of enforcement actions in the healthcare industry targeting both provider and insurer mergers. For example, on December 15, 2017, a federal district court granted the FTC's request for a preliminary injunction against Sanford Health's proposed acquisition of Mid Dakota Clinic, a large multispecialty group, which was appealed to the Eighth Circuit.

In addition to traditional "horizontal" hospital mergers between direct competitors, hospital/physician mergers and vertical arrangements have become more prevalent and attracted antitrust scrutiny. These types of deals may be considered more difficult for the agencies to challenge, however, notwithstanding the DOJ's recent appeal of the district court decision that cleared AT&T's acquisition of Time Warner.

This is not to say that provider transactions involving competitors should be considered nonstarters on antitrust grounds. Many of these types of transactions do not raise serious antitrust concerns, assuming the parties are in a position to demonstrate to the agencies that the transaction would lower costs and improve patient care and would not create a "must have" hospital or system. ◆

CONCENTRATION OF HOSPITAL MARKETS IS INCREASING



Source: https://www.ncci.com/Articles/Pages/II_Insights_QEB_Impact-of-Hospital-Consolidation-on-Medical-Costs.aspx

"The administration has raised concerns that healthcare providers might be becoming too concentrated and that state laws such as CONs and COPAs hurt competition. Healthcare providers need to be aware that enforcement at the antitrust agencies may be even more aggressive under the current administration."

Norm Armstrong, ***Partner, King & Spalding***

As Reimbursement Policies Shift, Providers Must Remain Vigilant and Engaged

Today's healthcare environment continues to advance in new directions, and after almost two years of the Trump administration in office, the one constant on the reimbursement frontier is change.

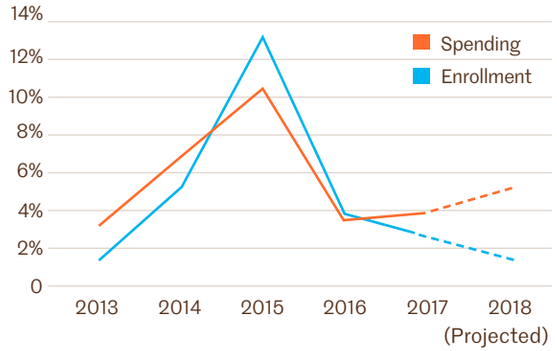
From reshaping state Medicaid coverage and reimbursement concepts to cutting the "red tape" and putting "patients over paperwork" in order to reduce burdensome documentation requirements and Medicare regulations for hospitals and other health facilities, the current administration's reform goals present both opportunities and challenges for healthcare providers. Providers need not be passive spectators of the changes happening around them, however. Instead, there are real opportunities to actively influence important aspects of this change. Since most change results in winners and losers, it is increasingly critical for providers to be proactive in molding and managing the new reimbursement policies that are unfolding.

CHANGES RELATED TO MEDICAID COVERAGE AND REIMBURSEMENT

- Medicaid already accounts for 17 percent of national health expenditures, i.e., $582 billion, and is projected to increase by nearly 70 percent to $996.2 billion by 2026. A major driver of the increasing cost is that the Medicaid population, like the U.S. population generally, is getting older and therefore is in need of more healthcare services, including the type of nursing home costs that Medicaid covers for medically indigent elderly people. By 2060, the number of Americans over age 65 is projected to more than double (from 46 million today to 98 million). And while the percentage change in Medicaid enrollments is projected to decrease over the next few years, Medicaid spending is projected to increase.

MEDICAID ENROLLMENT AND SPENDING IN THE SHORT TERM

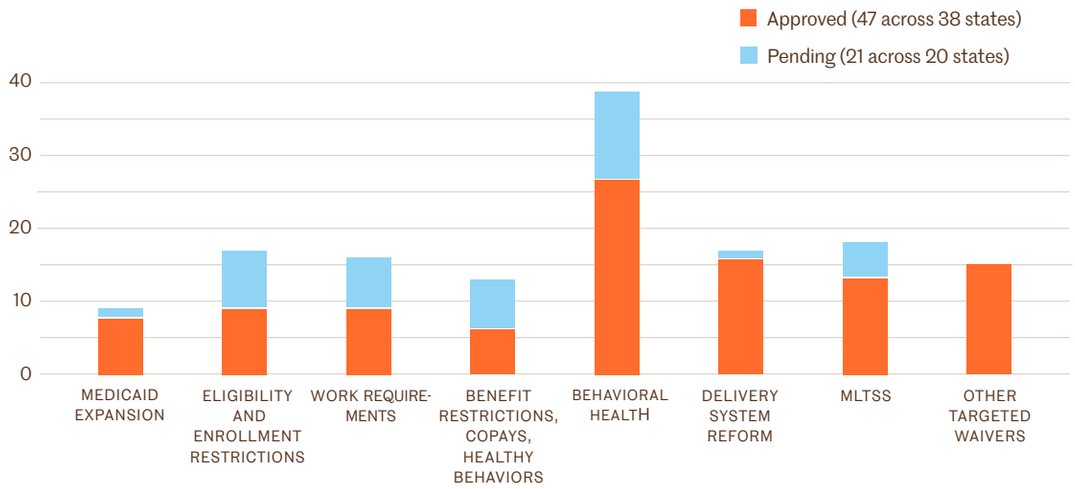
Percent change in enrollment projected to decline as percent change in spending projected to rise in 2018



Source: Kaiser Family Foundation, Medicaid Enrollment & Spending Growth 2017 & 2018, available at https://www.kff.org/medicaid/issue-brief/medicaid-enrollment-spending-growth-fy-2018-2019/.

- The increasing importance of Medicaid makes the changes within Medicaid — to Medicaid waivers, medicaid disproportionate share hospital (DSH) payments and the Medicaid Managed Care program — even more consequential.

APPROVED AND PENDING SECTION 1115 WAIVERS AS OF JANUARY 9, 2019

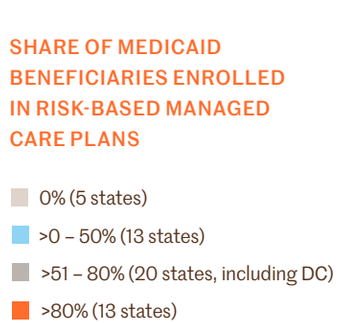


Source: https://www.kff.org/medicaid/issue-brief/medicaid-waiver-tracker-approved-and-pending-section-1115-waivers-by-state/

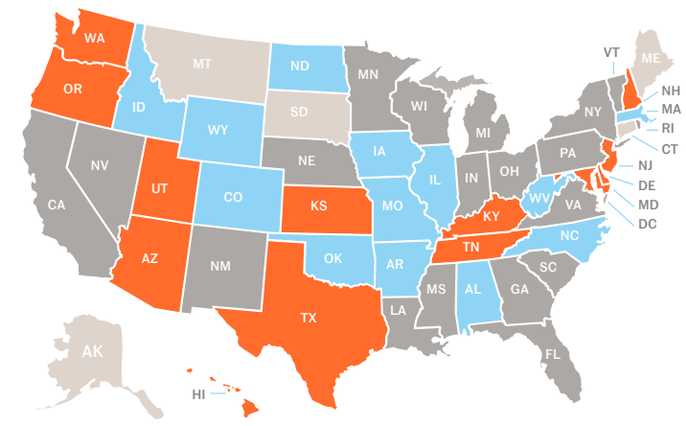
Medicaid Waivers

- The current administration has a very different view from the prior one of what the "objectives of the Medicaid program" are and which waivers will "promote" those objectives.
- This has led to novel waivers and waiver requests.
- These waivers have a substantial impact on not just beneficiaries but also on the providers that serve them. Healthcare providers, therefore, need to be actively engaged in shaping these waivers and must have a well-considered plan for operating under the waivers once they are adopted. If a waiver has a substantial adverse effect on a provider, the provider should carefully assess whether the waiver might be vulnerable to legal challenge. »

SHARE OF MEDICAID BENEFICIARIES ENROLLED IN RISK-BASED MANAGED CARE PLANS



Source: Kaiser Family Foundation, 10 Things to Know about Medicaid: Setting the Facts Straight, available at https://www.kff.org/medicaid/issue-brief/medicaid-enrollment-spending-growth-fy-2018-2019/



Source: https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-setting-the-facts-straight/

"The Trump administration has not been hesitant to shift dollars away from provider reimbursement, sometimes relying upon new and unexplored authority under the Medicare and Medicaid programs to cut rates, as was the case when CMS cut outpatient Medicare rates for 340B-purchased drugs. Efforts like these that go unchecked only breed more. If providers want to continue to provide outstanding patient care on margins that are already stretched too thin, they will have to become more proactive in the future. They'll have to create their own coalitions to challenge the agency and supplement the efforts of their associations."

Mark Polston, *Partner, King & Spalding*

Medicaid Managed Care

- Today, more than two-thirds of Medicaid beneficiaries are enrolled in a Medicaid managed care program (up from one half in 2011).
- CMS's recently announced "targeted enforcement discretion" regarding many of the requirements imposed by the 2016 Managed Care "mega-rule" is, therefore, extremely consequential. Providers should actively monitor the agency's application of that discretion and seek to avail themselves of the discretion when appropriate.
- Thirteen states already have a risk-based managed care enrollment that exceeds 80 percent. Providers, therefore, should carefully assess how they would be affected if states with a managed care saturation rate of 85 percent or greater are allowed to cut traditional Medicaid rates without oversight, as CMS has proposed.
- Providers with razor-thin margins will also want to give careful consideration to the administration's proposal to allow states to cut Medicaid base rates by up to 4 percent in a single year or 6 percent over two years without having to undergo public comment or beneficiary access monitoring.

REDUCING REGULATORY BURDENS

CMS has made several attempts to reduce provider burdens in an attempt to prioritize, to use the agency's phrase, "patients over paperwork." CMS has made significant progress in accomplishing this goal. But health systems should also be wary of reforms that the administration is promoting as reducing provider burdens but that also come at the cost of reduced provider payments.

The administrative burdens affecting providers that CMS has removed in the prior year include:

- No longer requiring written inpatient admission orders as a condition for Part A payment, recognizing that "discrepancies with the documentation of inpatient admission orders" have led to unnecessary inpatient claims denials.
- No longer requiring signed physician certification statements in patient medical records where similar information can be found elsewhere in the record.
- Overhauling hospital and physician quality measurement programs and the Medicare Electronic Health Record Incentive Program to eliminate collecting data on duplicative or "topped out" measures.
- Proposing to modernize the Medicare Conditions of Participation for multihospital systems by permitting unified infection control and other systemwide policies.

These reforms, along with others the agency has spearheaded, are a welcome development. But the agency has also couched other new initiatives as reductions in red tape that come at a tangible financial cost to providers. Most notably, CMS initially proposed to collapse all five evaluation and management (E/M) codes into one single code for all physician clinic visits. The agency's stated rationale for such a proposal was to reduce the amount of medical record-keeping physicians must do in order to support billing for a higher-intensity E/M. By limiting physicians to a single E/M code regardless of patient acuity, CMS believed that physicians would be able to treat more patients with the newfound time they were no longer spending on paperwork. Though the agency backed off from full implementation of this policy and only combined mid-level codes, the initial proposal is a sign of how the agency intends to wring savings from such "efficiencies."

The practical effect of such a proposal, had it been adopted in full, is that those providers whose physicians treat sicker patients — as is often the case with integrated medical staffs of large, safety net hospitals — will see a payment reduction while many smaller, independent physician practices that treat comparatively healthier patients will receive a payment rate increase. It seems unlikely that hospital medical staffs will be able to make up that lost revenue in additional patient encounters.

CMS estimates that its patients-over-paperwork initiatives will reduce the administrative burden to providers by $1.12 billion annually. This is projected to reduce provider man-hours by 53 million through 2021, which is equal to about $5.2 billion. That results in saving 6,000 years of burden hours over the next three years.

	BURDEN REDUCTION (DOLLARS)	BURDEN REDUCTION (HOURS)
2018	$183 million	10.8 million
2019	$1.6 billion	12.6 million
2020	$1.7 billion	15.3 million
2021	$1.7 billion	14.3 million
Total	$5.2 billion	53 million

COURTS CONTINUE TO SIGNIFICANTLY INFLUENCE CMS'S REIMBURSEMENT POLICIES

The courts have also been change agents that have created significant opportunities for providers. The cases that have spurred this change are almost always championed by a hospital or group of hospitals. While the road to final recovery may be a long one, the cases noted below will ultimately mean a large payout for hospitals.

"With significant changes in Medicare and Medicaid reimbursement being driven not just by the agency but by Congress and the courts as well, it's essential that providers employ the full spectrum of tools at their disposal to influence the direction of those changes."

Daniel Hettich, *Partner, King & Spalding*

- In *Saint Francis Medical Center v. Azar*, the D.C. Circuit evaluated Medicare's reopening regulation and opened up the possibility for hospitals to appeal to have base-year determinations corrected on a going-forward basis. 894 F.3d 290 (D.C. Cir. 2018).
- A district court upheld a challenge to a Kentucky Medicaid waiver, reasoning that the Secretary of Health and Human Services (HHS) failed to fully consider the effect of the waiver, which the state projected could result in roughly 95,000 people losing coverage by the state Medicaid program. The court nullified the Kentucky waiver and remanded the matter to HHS for further review. See Stewart v. Azar, 313 F. Supp. 3d 237 (D.D.C. 2018).
- Courts have invalidated different aspects of CMS's DSH policies that systematically disadvantage providers. See Allina Health Services, et al. v. Price, 863 F.3d 937 (D.C. Cir. 2017); Empire Health Foundation v. Price, 2018 WL 3846315 (E.D. Wash. Aug. 13, 2018). If *Allina* and *Empire* remain final, it would mean many millions of dollars in additional Medicare DSH payments for hospitals. ◆

POTENTIAL IMPLICATIONS OF ST. FRANCIS LITIGATION	
Number of Hospitals That Have a PRA and FTE Cap	1,119
Number of Hospitals With PRAs That Have Hit Their FTE Cap	753
Number of Sole Community Hospitals	223
Number of Medicare-Dependent Hospitals	161
Number of Hospitals Affected by PPS Standard Rate	~3,400

Continued Governmental Focus on Nonprofit Hospital Tax Exemption Benefits

Nonprofit hospitals face uncertainty as questions resurface in Congress and among state attorneys general about whether they do enough for their communities in return for the tax benefits they receive.

Congress targeted perceived abuses by nonprofit hospitals last year as part of the Tax Cut and Jobs Act by, among other things, creating a new executive compensation excise tax. At the same time, state attorneys general stepped up enforcement of charity care requirements and demanded strict adherence to conditions placed on hospital mergers and acquisitions. These actions may merely foreshadow more consequential reforms from Congress and more intense scrutiny by state regulatory authorities as pressure mounts for nonprofit hospitals to explain why they deserve tax-exempt status.

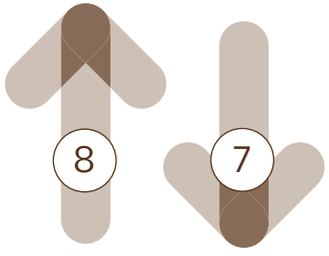
TAX CUT AND JOBS ACT

Efforts to reform the federal tax code started ominously in 2017 for nonprofit hospitals. Senator Chuck Grassley (R–Iowa) warned that some nonprofit hospitals "seem to forget that tax exemption is a privilege, not a right," while news outlets championed stories with headlines like "How Hospitals Got Richer Off Obamacare."

WHAT IS ENOUGH COMMUNITY BENEFIT?

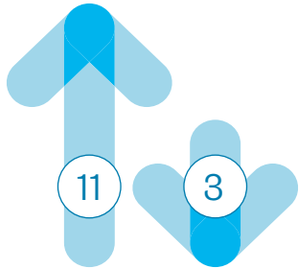
2014 and 2016 Form 990 filings for 15 of the largest nonprofit hospitals and health systems show mixed results on charity care, increases in Medicaid shortfall and total community benefit.

CHARITY CARE



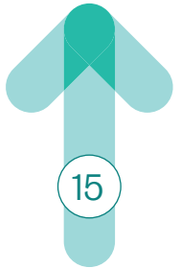
8 HOSPITALS SHOWED INCREASES IN CHARITY CARE, WHILE 7 SHOWED DECREASES

MEDICAID SHORTFALL



11 HOSPITALS HAD AN INCREASED MEDICAID SHORTFALL, WHILE 3 SAW DECREASES. 1 HOSPITAL REPORTED NO CHANGE

TOTAL COMMUNITY BENEFIT



ALL HOSPITALS DEMONSTRATED INCREASED TOTAL COMMUNITY BENEFIT SPENDING

"Nonprofit hospitals will see history repeat itself in 2019 in terms of a repeat focus on exemption standards with Senator Grassley set to chair the Senate Finance Committee."

Travis Jackson, ***Partner, King & Spalding***

Ultimately, Congress only nipped around the edges of the tax benefits that nonprofit hospitals enjoy when it passed the Tax Cut and Jobs Act. For example, Congress targeted perceived excessive executive compensation by imposing a new 21 percent excise tax on certain compensation packages over $1 million. Nonprofit hospitals also lost the ability to use advance refunding bonds to lower their borrowing costs, and they must now calculate unrelated business income taxes on an activity-by-activity basis. Still, each of these bites has real-world consequences, with some health systems potentially facing million-dollar tax bills.

GRASSLEY, HATCH REQUEST

These reforms may signal only the beginning of changes for nonprofit hospitals, particularly as Congress looks for ways to stem trillion-dollar deficits. For his part, Senator Grassley joined with Senator Orrin Hatch (R–UT) in early 2018 to request the IRS explain how it enforces existing exemption standards and determines "the degree to which nonprofit hospitals are benefiting their communities." The senators justified their inquiry by citing news reports of hospitals cherry-picking patients, using aggressive collection activities and reducing charity care.

STATE ATTORNEYS GENERAL

State attorneys general also stepped up investigations of nonprofit hospitals, with some filing suits over alleged failures to provide sufficient charity care. In 2015, the attorney general of New York probed whether two community hospitals provided appropriate assistance for patients with limited English proficiency and offered sufficient charity care to indigent residents. More recently, the attorney general of Washington state filed suit in 2017 against a charitable health system, alleging it violated state laws governing charity care.

In other instances, state attorneys general are using their authority to impose strict community benefit requirements on hospital mergers and acquisitions and then refusing to modify those conditions after a transaction closes, even if market conditions change. The attorney general of California denied efforts in 2018 by three hospitals to reduce charity care requirements that the hospitals argued were unnecessary in light of increased insurance coverage under the Affordable Care Act. The attorney general rejected these arguments and required the hospitals to donate over $5 million to nonprofit organizations that provided medical services to low-income and homeless residents in their communities.

Nonprofit hospitals should expect heightened scrutiny of their activities to be the new normal. Navigating this environment successfully requires nonprofit hospitals to examine their existing operations in light of federal and state requirements and to work to inform key stakeholders of the specific benefits they provide to their communities. Nonprofit hospitals must also stay informed about federal and state legislative proposals and educate their representatives about the practical impact these proposals may have on their operations. ◆

Are You In, or Are You Out? Providers Face Difficult Choices When It Comes to Tiered Networks

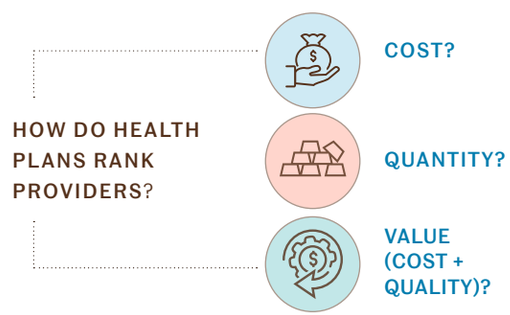
Facing persistent demands to limit the inflation of healthcare spending, many commercial health plans are developing tiered networks, touting them as a way to steer patients to providers that have better quality and lower costs. These products offer significant opportunities for providers to increase the number of patients seeking their services. For example, if a provider is in the highest tier of a tiered network and the benefit design of the tiered network creates a substantial differential in the cost of seeking services from a provider in differing tiers, then that provider is going to feel the beneficial effect of the "steerage" created by the tiered benefits.

"Tiered benefit networks are not always winning propositions. Healthcare providers that have the right to choose whether they will participate in a tiered network need to weigh carefully the benefits and costs of the tiered benefit structure."

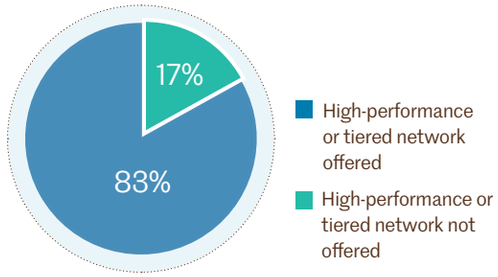
John Barnes, *Partner, King & Spalding*

But there are drawbacks as well. For tiered networks, health plans are not always forthcoming about the methodologies they employ to rank providers, making it difficult for providers to decide whether they want to participate. Some methodologies downplay factors that are of significant importance to both patients and providers. For example, ranking methodologies frequently rate average costs significantly higher than quality. So a provider that has made significant investments in quality may be ranked lower than another provider that offers lesser quality simply because the other provider has lower average costs.

A fundamental hurdle preventing a provider from doing anything about tiered networks is the fact that many managed care agreements allow health plans to include a provider in all networks developed by the health plan without the provider having any say in whether they want to participate in a particular network, such as a tiered network. But many providers have decided they do not want to be



2018 BENEFIT PLANS AMONG LARGE EMPLOYERS



forced to participate in every product being offered by a plan. When providers retain this right of choice, they can engage in a meaningful decision-making process about whether to participate.

Consider the Ranking Methodology

Providers should carefully scrutinize the methodology the health plan uses to rank providers into tiers in order to ensure that the methodology fairly addresses the value the providers bring to the network. If the methodology for assigning a ranking is inherently flawed and causes the provider to be ranked in a lower tier, the provider may decide that being a participating provider in the lower tier is not worth the "cost" (in the form of the discounted rates) of participation.

"The decision on whether to have a contract limited to certain products or to give the health plan or the provider the right to choose leads to a variety of potential structures. This can also lead to legal disputes when the language used does not match the business goals or desires of one or the other party. The time spent at the outset negotiating what products will be included or excluded can substantially reduce the potential for these type of disputes."

Glenn Solomon, *Partner, King & Spalding*

"Providers should know the basis for a plan's ranking system. Unlike the tiering of prescription drugs, physician and hospital services are less commodity-like and require judgements on the complex factors underlying meaningful cost and quality comparisions. Depending on what factors a plan analyzes and the process used to determine the rankings, a provider's tier may or may not be reflectivie of the actual quality of services provided."

Kathy Poppitt, *Partner, King & Spalding*

Understand the Benefit Differential

Providers that are ranked in the highest tier will want to ensure that they are receiving appropriate steerage in the form of a substantial benefit differential between the highest and lower tiers. When providers are ranked in a lower tier, the decision-making process will depend largely on whether the in-network benefit, albeit with a higher cost share, provides sufficient steerage to justify extending the discounted rate to the benefit plan.

Know the Intended Market for the Benefit Plan

Health plans often create tiered networks for specific employer groups. If the provider knows that the employer offers multiple health plans to its employees and the other health plan options also include the provider in the network, the provider may be confident enough in those employees' loyalty to the provider that the provider will decide to decline participation in a tailor-made tiered network.

Providers Must Be Proactive about Tiered Networks

Providers that are able to successfully navigate the complexities of tiered networks using proactive contracting strategies are going to be the most successful at gaining an edge in the competition for healthcare dollars. ◆

Transactional Activity in Healthcare to Remain Strong in 2019

Mergers and acquisitions and other transactional activity in healthcare and life sciences increased throughout 2018, and we expect further increases in 2019 as the potential changes to healthcare policy from the new Congress become clearer.

- Global healthcare M&A deal volume reached $332 billion in 2017, approaching record levels. Through the first half of 2018, deal volume was up 9.4 percent over 2017 volume.
- After the FTC blocked several horizontal integration proposals among payers, many are now seeking to vertically integrate by acquiring providers along the care continuum. It remains to be seen how these plays will impact the healthcare delivery system over the long run, but it is clear that payers are getting into the healthcare delivery business in a way they have not been previously (outside of the Kaiser Permanente model).
- Insurance companies appear to be interested in getting involved in a broad range of healthcare provider services, from physician services, as demonstrated by United's acquisition of HealthCare Partners, to retail healthcare, as demonstrated by CVS's merger with Aetna, to home health and hospice, as evidenced by Humana's acquisition (together with some private equity funds) of Kindred at Home and Curo. This may enable the payers to control delivery of care in lower-cost outpatient settings rather than inpatient settings. Outside of Kaiser, there are few examples of payers acquiring higher-cost healthcare delivery providers like hospitals or other institutional healthcare providers.
- We are watching with interest how the provider community, particularly the hospital industry, reacts to the changes brought about by insurance company moves to vertically integrate. It could drive further consolidation in the hospital sector, as hospital chains seek to grow scale and leverage with payers.
- Many large not-for-profit hospital chains continue to grow their regional footprint. Ochsner recently concluded a joint venture with Louisiana State University, and the boards for Baylor Scott & White Health and Memorial Hermann Health System have announced the signing of a letter of intent to merge. There are similar examples across the country.

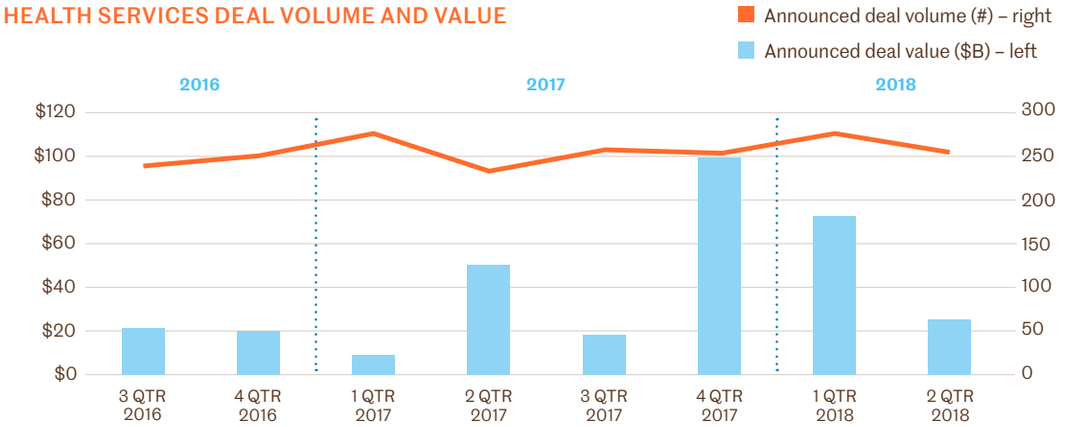
"Academic medical centers are seeking hospital system partners, both nonprofit and for-profit, to increase operational efficiencies and to affiliate with larger networks in their geographic markets. We have been working with both the AMCs and the hospital system partners in establishing these new operating entities."

Jay Harris, ***Partner, King & Spalding***

"While M&A in the healthcare sector remains robust, in some markets the low-hanging fruit of available and willing acquisition targets has already been picked, causing providers to turn to joint ventures, affiliations and other collaborations as a primary strategy for system growth and expansion."

Torrey McClary, ***Partner, King & Spalding***

HEALTH SERVICES DEAL VOLUME AND VALUE

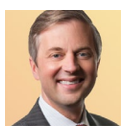


Notes: Excludes spin-offs, add-ons, loan-to-own transactions and acquisitions of bankrupt assets; based on announcements date; includes announced deals that are completed or pending, with data subject to change; deal value does not account for deals with undisclosed values.
Source: Dealogic, AVCJ; Bain analysis.

- Many investor-owned hospital companies continue to divest hospitals in non-core areas to focus on key geographic markets. Most are also increasing acquisitions of ancillary service providers, with a particular emphasis on building out their outpatient and retail capabilities.

"Healthcare reform is by no means over; it has only become more complicated! Medicare Advantage and population-based reimbursement programs continue to drive new affiliation models focused on increased consumer and provider risk. With private equity now heavily entering the provider market, alternative affiliation models require more creativity than ever. 2019 will be both an interesting and challenging year for providers."

Phillip Street, ***Partner, King & Spalding***



"As always, the healthcare market continues to evolve. Significant cost pressures, coupled with a need to control patient outcomes to optimize value-based pay, are driving vertical and horizontal integration in the industry."

Thomas Hawk, ***Partner, King & Spalding***

- Analysts' ratings for investor-owned hospital stocks have generally been favorable, with most stocks in the sector receiving buy or hold recommendations. Analysts are also predicting an increase in earnings per share for hospital stocks in the next fiscal year.
- Credit rating agencies' views on the nonprofit hospital sector have been mixed recently, but a positive trend seems to be developing. Moody's changed its outlook on the sector from stable to negative at the beginning of 2018 due to an increase in credit downgrades during 2017. Fitch Ratings announced a negative outlook at the beginning of 2018 but announced in August that it was seeing more frequent upgrades to credit ratings during the year. S&P has maintained a stable outlook for the sector, noting that reserves are strong but that operating margin pressures are expected to continue.
- Private equity firms have shown a significant interest in the acquisition of physician practices, particularly those practices like dermatology, orthopedics and ophthalmology with significant amounts of ancillaries.
- Strategic and investor interest in electronic health record and billing companies remains high. ◆

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