Although we recently passed the fifth anniversary of the launch of HealthCare.gov, the healthcare landscape remains anything but a clear picture. Questions surrounding delivery models, quality of care, technological innovation and pricing transparency continue to swirl all around us.

Beyond the unsettled regulatory and legislative environment, the healthcare system itself struggles to address all the issues listed above, while still being able to find a way to pay for it all.

For more than five decades, Waller has been helping healthcare companies thrive by successfully navigating challenging obstacles and remaining ahead of the curve in the ever-changing world of healthcare delivery.

This report is a reflection of our desire to keep you informed about the road ahead. We talked with attorneys from a cross-section of our practice areas to get a sense of the important milestones from 2018 and to get their predictions for what’s in store for 2019.

We invite you to explore our inaugural edition of The Healthcare Industry: A Look Back. A Look Ahead. We hope these thoughts will spark conversations within your own organizations, and we look forward to sharing insights with you during the year ahead.

On behalf of everyone here at Waller, we wish you a happy, healthy and prosperous 2019.

Sincerely,

Ken Marlow  
Chair  
Healthcare Department

Colin Luke  
Practice Group Leader  
Healthcare Compliance & Operations
While buzzwords like consolidation and price transparency continue to dominate headlines, major players throughout the healthcare ecosystem are working tirelessly behind the scenes to deploy creative and complex service methods that leverage a smarter, more holistic approach to care. The goal? Control escalating costs and deliver tangible value to patients – all while maintaining a healthy balance sheet.

The challenges are many: navigating market consolidation, raising capital to invest in new technology and attracting and retaining top talent – all against a backdrop of an increasingly uncertain political and regulatory environment. But the reward – providing high-value care that engages patients – is arguably as great as it has ever been.

To answer the question of what the healthcare industry will look like in 10 years, it is just as critical to examine what will remain the same. These trends should be with us for a while:

- **Understanding & bolstering a patient’s continuum of care**
- **Emphasizing value over volume**
- **Gathering & leveraging ever-increasing mounds of data to inform better decisions**

As a majority of the population gets older and life expectancy increases, the need to innovate across technology, operations and policy fields becomes vital.

In the pages that follow, we draw on our nation-leading healthcare experience to highlight some of the key issues faced by the healthcare industry in 2018 as well as outline the myriad opportunities and challenges the industry will face in the years to come.
Obamacare survives – mostly – and gridlock returns

It’s no secret that healthcare companies are operating in an increasingly uncertain regulatory environment. Marked by an extraordinary mix of political and policy trade winds, they are constantly looking for new ways to track outcomes and operate effectively amid a movement to value-based care. But with that change comes the potential for new forms of scrutiny, greater consumer pressure and a serious need for innovation.

In 2017, the late Sen. John McCain (R-Ariz.) put a damper on the GOP’s years-long effort to repeal and replace the Affordable Care Act. Since then, healthcare has become arguably more polarizing between political parties, with both sides of the aisle rallying behind respective efforts to limit – or expand – the law’s reach.

Given the results of the 2018 midterms, we don’t expect any dramatic changes any time soon: Republicans in Congress will continue looking for ways to reduce Medicaid and Medicare spending while the Trump administration will continue to chip away at the Affordable Care Act whenever possible. The wild card, of course, is a recent federal court decision in Texas that ruled the ACA unconstitutional – a decision that could ultimately put the law’s fate back in the hands of the Supreme Court. Democrats, meanwhile, with a new House majority, will inevitably call for a greater role for government in healthcare delivery and payment and have already introduced a number of bills related to their Medicare for All proposal. However, the reality of a divided government means that healthcare reform will mainly be used as a rallying cry for the elections in 2020 for now.
Still, on a practical level, we do expect significant attention on Medicaid waivers, including work requirements and alternative benefits for specialized populations. We may also see modified expansion efforts in the states that have not expanded Medicaid by incorporating alternatives in the state waivers, such as the Arkansas model.

Also, there is likely going to be additional activity on pricing transparency and no “surprise” billing of patients by payors or providers. There is bipartisan consensus on this effort as well and broad support for drug pricing reform.

So, how do healthcare companies prepare amid the power struggle between two very different governing philosophies? The safest bet? It’s all about quality.

It’s been clear for a while now that Medicare will no longer pay based on volume alone – one in three healthcare payments is tied to an alternative payment model. We believe in the years to come that a higher percentage of Medicare patients will join pilot programs designed to promote quality outcomes. In addition, private insurers have already incorporated payment provisions into their contracts that are based on quality.

How to get it right on quality

Healthcare companies are working diligently across a number of areas because of reimbursement pressures, the movement of inpatient care to the outpatient setting and the need to uncover new ways to pay for service.

Not all providers have the scale or deep pockets to own myriad access points across service areas, so the time for collaboration is now. In fact, healthcare regulators under the Trump administration have demonstrated a willingness to ease regulatory restrictions in the name of such collaboration.

The U.S. Department of Health and Human Services has signaled that it could reduce or even eliminate some of the existing barriers to provider alignment across different systems.
The Centers for Medicare and Medicaid Services, in particular, is reviewing certain aspects of the Stark Law which sometimes act as a barrier to alignment among providers and healthcare companies that don’t share common ownership. As it stands, Stark prohibits physicians from making referrals for certain services covered by Medicare to any entity in which the physician (or an immediate family member) has a financial relationship. While the proposed changes haven’t been announced yet, the goal is to create more opportunity for value-based payment arrangements, which tie payments to quality of care and reward efficiency and effectiveness.

**FOR FURTHER READING**

*CMS seeks input on Stark Law and other regulatory issues*

*Justin R Hickerson & Jesse C. Neil* from the Waller Healthcare Blog

Revising the Stark law would not be without challenges, particularly as it pertains to how the federal government defines fraud and abuse. For example, if a provider is given a flat-fee to care for orthopedic patients during a two-year period, that provider could be driven by financial motives – i.e., not wanting to provide too much care for its rate of reimbursement. These types of circumstances raise new areas of potential regulatory scrutiny and represent potential risk that regulators will need to consider.

Along those lines, CMS also has announced that it hopes to reduce regulatory barriers for accountable care organizations and other providers that take on additional risk in a value-based reimbursement model. Compliance flexibility and waivers from CMS will serve as a reward for providers who engage in two-sided, or full, financial risk models, CMS Administrator Seema Verma told the Accountable Care Learning Collaborative last summer. As it stands, many value-based pilot programs have yet to turn a profit. By giving providers more skin in the game, regulators are encouraging additional innovation in the market, whether intentional or not. In these instances, the government has said that it is more likely to ease the regulatory burden if there is a shift in risk to private entities.
A key area for investment related to collaboration in coming years will be population health, or the alignment of care across multiple providers and payers for a defined population. In such arrangements, healthcare outcomes tend to be specific to a distinct group and distributed across that group as a whole.

We are not suggesting this is a new idea. In order to accelerate these efforts and improve and enhance care across different patient demographics, however, CMS has said that organizations should begin implementing “data-driven” tools and strategies to both identify challenges and strategize solutions. In March, for instance, Blue Button 2.0 was launched to allow Medicare beneficiaries to take charge of their own data by allowing them to access and share their claims data in a secure format.

The use of new technology and ongoing collaboration in a population health-driven environment comes with a number of potential regulatory roadblocks such as those involving discrimination, privacy, breach of contract and fraud and abuse.

For example, the mere operation of a cohesive provider and payor network comes with a number of issues related to the structure of the system, tax and antitrust laws. The sharing of data across providers in the system could involve privacy laws such as HIPAA, as well as laws at the state level. The creation of referrals across the system could run afoul of fraud and abuse laws and outcome-based “financial incentives.”
As healthcare providers begin to pursue this area more aggressively in the coming years, it is important they put into place both internal and external tools, safeguards and strategies to avoid potentially reputation-damaging pitfalls.

The following actions can help organizations manage security risks proactively:

- Conduct sufficient regular enterprise-wide security risk analysis; OCR has made it clear this is not a “check the box” activity and must be comprehensive.

- Integrate a security and risk management plan into business processes to identify, monitor and address identified risks.

- Implement security safeguards such as encryption; this is imperative in light of increased cyberattack frequency.

- Implement a robust business associate management program to ensure BAAs are in place as appropriate and address breach/security incident obligations.

**FEDERAL & STATE REGULATORY POLICY SUMMARY**

The move to payment based on quality is inevitable and comes with a number of new regulatory impacts around aligning care, collaboration across service providers, price transparency and population health.

Providers across the spectrum, and particularly decision makers at hospitals, should consider these changes and begin to implement technology, processes and procedures to prepare for what’s to come.
Priorities for 2019: Diagnostic labs, long-term care, opioids and executive accountability

No one would call the Department of Justice a slave to fashion, but it does chase trends over the years. A focus on the ongoing opioid epidemic is a clear priority, with DOJ announcing the “largest ever healthcare fraud enforcement action involving 601 charged defendants across 58 federal districts, including 165 doctors, nurses and other licensed medical professionals, for their alleged participation in healthcare fraud schemes involving more than $2 billion in false billings. Of those charged, 162 defendants, including 76 doctors, were charged for their roles in prescribing and distributing opioids and other dangerous narcotics,” according to a DOJ release.

Moreover, the DOJ Criminal Division announced in October that it was creating an Appalachian Regional Prescription Opioid Strike Force “made up of prosecutors and data analysts with the HCF Unit, prosecutors with the nine U.S. Attorney’s Offices in the region, and special agents with the FBI, HHS-OIG and DEA.”

Based on this priority, providers operating in the pain clinic space or associated practices would do well to ensure robust compliance and medical records programs, and hospitals and other entities should do the same.

Another area of recent focus – and one that we believe will continue to see activity in the years to come – is the diagnostic lab sector, where the profit margin for a number of tests is incredibly high. Particularly in this sector, the government is using sophisticated data analysis techniques to uncover potentially problematic billing and referral patterns.
Finally, the government continues to focus heavily on the long-term care space, with particular attention paid to the long-term acute care hospital (LTACH) and skilled nursing facility (SNF) sectors. The reimbursement guidelines and regulations for LTACH and SNF facilities have become more and more complex over the last several years and — as is generally the case — HHS-OIG and DOJ seek out enforcement opportunities in the sectors where the most mistakes are often made.

On a broader level, the government has shown considerable signs that it will continue to focus future efforts in two key areas: holding individuals and companies accountable and using data analysis to spot irregularities. Healthcare companies across all sectors should be primed and ready.

A push for individual accountability

While some initial signals appeared to indicate that DOJ may be backing off on the 2015 Yates Memo regarding executive accountability, events toward the end of 2018 indicate that the DOJ will likely continue to aggressively target high-level executives when it can. In May 2018, Bloomberg published an article based on a study from Syracuse University reporting that “the number of white collar-prosecutions is on track to hit a 20-year low under President Donald Trump, after reaching a high in 2011 during the Barack Obama administration.” The article quoted Deputy Attorney General Rod Rosenstein as saying that the administration would “reward companies that try in good faith to deter crime.”

Moreover, in response to a rising number of qui tam lawsuits, in January 2018 various news outlets leaked a memo authored by Michael Granston, head of the Commercial Litigation Branch’s fraud section, which sets forth a detailed analysis of the situations in which the Department should consider dismissing qui tam actions brought under the False Claims Act (FCA) pursuant to 31 USC 3730(c)(2)(A).

This provision allows the Justice Department to dismiss actions brought by a relator. Until now, it has been rarely exercised.
The Yates Memo (2015), however, is still in full effect:

“One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing. Such accountability is important for several reasons: it deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions and it promotes the public’s confidence in our justice system.” – SALLY YATES

On one hand, under the Yates Memo, the government has outlined a more muscular approach, whereas the Trump administration has signaled that the DOJ will be more vigorous in actively dismissing *qui tam* complaints.

So, how should healthcare companies react? A recent Florida lawsuit provides some clues. Early in 2018, the DOJ alleged that a private equity-backed pharmacy company – Diabetic Care Rx, LLC d/b/a Patient Care America – violated the federal Anti-Kickback Statute. In an unusual move, the government also named the company’s private equity investor, Riordan, Lewis & Haden, Inc. (RLH), as a defendant.

While the case will certainly serve as a teachable moment, allowing those parties to learn from RLH’s mistakes, it also could signal a continued shift toward complaints filed against people – investors, executives and officers alike. As such, it is important for healthcare companies to revisit compliance programs and the relationship between investors and operators.

Regardless of whether the decline in federal healthcare fraud enforcement remains steady under the Trump Administration, it has become clear that other regulators, including those at the state level, will likely remain active.
FOR FURTHER READING:

LISTEN: Healthcare providers are watching administration’s movements closely

John E. Haubenreich & Jesse C. Neil from the Waller Healthcare Blog

In early 2018, for example, Forbes reported that the California Department of Insurance (CDI), “filed a state-court lawsuit against pharmaceutical manufacturer AbbVie, alleging that AbbVie used illegal kickbacks to promote the use of its rheumatoid arthritis drug Humira.” The case highlights the willingness of other types of regulators to pursue cases in light of the decline of overall enforcement activity. We expect that activity to grow in Tennessee and in other healthcare-rich states.

Big Data is watching you

The Justice Department has long pursued burgeoning sectors, where both traditional and non-traditional players pour new investment dollars. The move to outcome-based care could have serious ramifications for how and what the DOJ targets and could create significantly more buzz around data-related fraud.

Namely, the increasing use of electronic health records and other computer systems has created new opportunities for regulators and third-party auditors to detect fraud and abuse and has increased potential instances of fraud as companies rely more heavily on data. In these cases, companies will need to be conservative about how they classify services, especially if regulators are looking for people manipulating outcome data.

But how much of that is fraud and how much of it is simply a result of unintentional human error? In the last 10 years, we’ve seen a rise in the use of more sophisticated tools to uncover fraud or alleged fraud. But from a defense perspective, a lot of what is uncovered falls into the category of human error. Some courts are beginning to take that into consideration, particularly in the U.S. Court of Appeals for the Second Circuit, which has already shown signs of taking a more deliberate approach when distinguishing between fraud and simple human error.
GOVERNMENT INVESTIGATION SUMMARY

While it can be difficult to predict where the government will focus its time and resources, healthcare companies can expect a continued regulatory focus in the lab and genetic testing area, a new spotlight on individuals such as investors and executives, as well as an intensified focus around data-related fraud in a value- or outcome-based provider model.

As such, healthcare companies should place a greater emphasis on technology that can both track outcomes as well as provide valuable information should questions arise surrounding compliance or internal investigations. While it’s standard practice for providers to have written compliance plans, one of the most critical steps is to have a mechanism for routinely auditing your operations to ensure that the important elements of the compliance plan are being carried out on a regular basis.

The other important component is to have a plan in place to respond when issues do arise or a healthcare organization is contacted by the government. Taking the right steps early on can set the course for a review process that is productive and successful versus an adversarial encounter that can be counterproductive in the long run.

MERGERS & ACQUISITIONS

Deal activity will likely slow in 2019, but it’s just a breather

There are numerous macroeconomic pressures that can make healthcare mergers and acquisitions a greater financial risk – ongoing trade disputes, a rise in interest rates and uncertainty surrounding the role of the federal government in healthcare.

Even against this backdrop, M&A activity continued in 2018, demonstrating that providers, and in particular hospitals, are consolidating out of necessity.

With 36 announced transactions, the first quarter of 2018 was the most active first quarter for hospital
M&A activity in a decade, according to Ponder & Co. The pace continued in the first half of 2018, with 50 announced transactions, according to additional data compiled by consulting firm Kaufman Hall. By year’s end, the pace had slowed, but only by comparison to previous quarters.

The activity is primarily a result of the need to create scale in today’s healthcare environment. As noted in a report by Deloitte, 40 percent of hospital acquirers cited increasing market share as a primary driver of a deal. Meanwhile, “nearly a third of surveyed executives from acquired hospitals sought M&A to improve their access to capital, the top-reported driver among those acquired.”

Some onlookers believe that the overall pace of healthcare M&A can’t possibly continue at a similar rate in coming years. A recent Capital One Healthcare survey found almost 60% of healthcare investors and operators believe M&A activity will either stay the same or decline in 2019. We believe, however, there remain a number of subsectors slated for abundant activity, particularly in the healthcare information technology space, home health and hospice, acute care hospitals and physician practices.

Since 2015, there has been an average of one megadeal per quarter in healthcare, according to a PWC report.
The future of acute care

In the acute care space, activity hasn’t been as robust as it probably should be given the number of acute care hospitals in the market. More and more providers are coming to grips with the realities they face in terms of reimbursement, competition and the rapid build-out of regional networks.

With that has come quite a bit of pain. From 2013 to 2017, 64 rural hospitals closed, according to the U.S. Government Accountability Office, which is more than twice as many as during the previous five-year period. In 2018, the trend continued with more than two dozen hospitals filing for bankruptcy protection or announcing their closure.

For a deeper look at how local communities can protect and strengthen healthcare locally, visit preservinghealthcare.com – a joint effort of Waller, Healthcare Management Partners, LLC and Taggart, Rimes & Graham.

Our expectation is that we’ll actually see further consolidation – although it’s safe to say that acquirers may get more selective as the number of opportunities with low-hanging fruit begin to diminish.

Part of the reality is that in recent years, managed care companies have been working to push care out of expensive hospitals and into cheaper outpatient settings. Those companies control an increasing portion of patients that are purchasing Medicaid and Medicare plans directly versus going through the federal government. At the same time, new technology has made it easier to perform care outside of the hospital.

For example, Humana doled out $4.1 billion in 2017 to purchase Kindred Healthcare. As part of the deal, Humana “split the health-care company in two, hiving off its long-term care and rehabilitation hospitals from its other business.” Meanwhile, CVS Health wants to keep patients out of the emergency room and is using its $79 billion acquisition of Aetna Inc. “to do more at revamped, upgraded drugstores.”

That activity is forcing hospitals to take action. Increasingly, acute care providers are investing and partnering in areas such as home-health and urgent care. One prime example is the partnership between LHC Group and LifePoint Health. In the first two years of their partnership, they have grown from 20 home health and 10 hospice locations to 33 home health and 14 hospice loc
Acute care providers are also looking to join massive regional networks. In places like Pennsylvania and Texas, there has been substantial consolidation of regional providers, resulting in so-called “mega-systems.” This year in Texas, Baylor Scott & White Health and Memorial Hermann Health system announced a merger that will encompass 68 hospitals in 30 Texas counties, employing more than 73,000 people statewide when it is completed in 2019.

So, will the acute care model disappear, sopped up in a wave of consolidation? Not quite. Undeniably, the model will change. An increasing focus on regional partnerships could provide the scale hospitals need to be successful. There’s no question that there will always be a place for acute care hospitals. What new entrants are signaling, however, is a willingness to leverage customer information and relationships with virtually everyone in the United States. Amazon’s unique perspective, for example, combined with its nearly unfettered access to potential patients will likely accelerate the focus of all providers on the patient, acute care included.
While some in the healthcare industry don’t believe the pace of consolidation can possibly continue, there will remain pockets of robust activity driven by the need to gain market share, generate revenue and drive innovation. Expect the number of acute care hospital and information technology deals to rise in the coming years.

When seeking potential partners, we recommend providers consider a number of factors, including the impact a deal would have on market share, reputation, service lines, capital and the ability to innovate at the delivery level.

PRIVATE EQUITY & VENTURE CAPITAL

Host of players bring opportunity in key sectors

Private equity and venture capital firms are pouring billions of dollars into the U.S. healthcare system in what’s become an all-out race to improve the bottom line of providers across the sector and to place bets on the next “big thing.” New investors are entering the industry in hopes that their decades of operational experience in other sectors can translate into success in healthcare, which has for years lagged behind in innovation and efficiency. In fact, Bloomberg reports that in the first half of 2018 alone “more than $10 billion was invested in health-care deals” and an “additional $1 trillion of investable capital currently is available for deployment in healthcare.”

Over the past few years, private equity investors have focused on capturing additional share in high-margin physician practice markets that have upside growth potential. That activity has occurred largely in two areas – either in specialties that have a surgical component or in specialties that have a hospital-based component. It’s a strategy investors are looking to replicate in new subsectors.

Hospital-based investment activity is ongoing in areas such as emergency medicine, radiology and anesthesia, where physician groups often have exclusive contractual arrangements with health systems or hospitals. Such agreements make these specialties attractive to outside investors because they help create certainty and reduce risk.
The other area seeing significant activity (and where we expect activity to continue) is physician groups that have a surgery component. These types of deals are high margin for investors and can provide practices with the cash they need to invest in the business, particularly in new technology.

As such, anesthesia, dental, dermatology, emergency medicine, radiology and vision services have all been pretty hot over the last five years. In 2019 and beyond, we anticipate widespread efforts to replicate that success in new areas, such as gastroenterology, urology and even orthopedics.

Orthopedic practices in particular create the opportunity for investors to leverage ancillary services—such as radiology or physical therapy. This sector also relies heavily on hospital relationships and is anticipated to play a larger role in the healthcare system as care moves outside of hospital walls. On top of that, the country’s aging population could create a spike in demand for this type of care.

Large investment firms, meanwhile, are looking beyond subsectors of ambulatory and surgical care. Recently, we’ve witnessed considerable activity from public investment firms making very large investments. For example, Apollo Global acquired LifePoint Health in a $5.6 billion deal to expand its rural U.S. hospitals business, the latest in a series of bets by private equity firms on healthcare. Following the deal, Apollo merged LifePoint with another acquisition, RCCH HealthCare Partners, to create a network with more than 80 non-urban hospitals in 30 states.

Hospital companies make an alluring target, given the benefits of lower tax rates than other industries and their insulation “from global trade uncertainties,” Reuters reported. According to data from PitchBook, an investment deal tracking platform, one of the largest deals of this type included Humana,

Illinois-based Decatur Radiology Physicians (DRP) was acquired by Envision Healthcare, a company backed by KKR & Co. Waller represented DRP by negotiating and structuring the sale agreement and working with DRP’s financial advisor, Edgemont Capital Partners, L.P., to finalize the deal. DRP’s physicians provide comprehensive radiology services for the sole hospital in Decatur, IL, with over 140,000 reads annually.
TPG Capital and Welsh, Carson Anderson & Stowe, which joined forces in 2018 “to acquire Kindred Healthcare for $4.1 billion and Curo Health Services for $1.4 billion.” KKR also joined the fray “with a $2.4 billion add-on acquisition of American Medical Response, combining the business with portfolio company Air Medical Group.”

Given these conditions, it is likely that investment firms will continue their foray into the healthcare system. Even the American Medical Association has taken notice. The group in early 2018 “adopted a resolution to study the impact of corporate investors — including private equity, public companies, insurers and health systems — taking a majority or controlling stake in companies that manage physician practices,” according to Modern Healthcare.

PRIVATE EQUITY & VENTURE CAPITAL SUMMARY

Rampant investment activity across the healthcare sector from a number of different players will continue in the coming years. Notably, private equity firms could play a greater role in the consolidation of hospital systems, as they seek to replicate early physician practice success in new areas. At the same item, venture dollars will flow to technology and areas designed to help service providers better track outcomes and reduce costs.

CONCLUSION

The healthcare system is changing. Healthcare companies – particularly providers and investors – across the spectrum are looking for ways to drive down costs and create efficiency. These efforts are creating a groundswell of support for the move to value-based care. Such a system presents a number of challenges and opportunities for the healthcare industry.

Providers and related companies that take a proactive approach to this change will be poised for success. That means investing in new technology, finding smart partners, reviewing compliance programs and anticipating regulatory burdens before they become reality. It’s not an easy task.
We would love to hear your thoughts and feedback on this year’s report. You can reach us at WebsiteEditor@wallerlaw.com.

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