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The ACA in 2019: Expanded Flexibility or Erosion?

—Katrina Pagonis and Stephanie Gross, Hooper Lundy & Bookman PC

In the final weeks of 2018, Judge Reed O'Connor of the Northern District of Texas shook expectations around the future of the Affordable Care Act (ACA), ruling that the law is invalid in its entirety following the repeal of the individual mandate penalty. At the time of this writing, the court has not issued an injunction, and the administration has pledged to continue implementing the ACA. Meanwhile, the Trump administration is continuing to explore ways to expand states' flexibility and limit various ACA requirements, while the return of divided government following the 2018 mid-term elections may open the door to increased congressional oversight. In addition, states' experiences under the ACA are set to diverge further in 2019 with some states looking to use waivers to temper the ACA's impact while others seek to incorporate ACA protections into state law or implement Medicaid expansion.

Continuing ACA Challenges. After eight years, litigation challenging the ACA continues with *Texas v. Azar*—a challenge brought by 20 states and defended by 16 intervenor states and the District of Columbia. On December 14, 2018, Judge O'Connor held that the ACA's individual mandate is no longer a constitutional exercise of Congress' taxing power with the penalty eliminated, effective January 1, 2019. Judge O'Connor then surprised observers by rejecting the Department of Justice's (DOJ's) argument that only the ACA's guaranteed issue and community ratings should be invalidated with the individual mandate and instead invalidating the entire ACA as inseverable from the individual mandate. At the time of this writing, litigation is ongoing before Judge O'Connor, but observers expect the case will be appealed to the Fifth Circuit and may ultimately be decided by the U.S. Supreme Court. Maryland has separately filed suit in the District of Maryland to obtain a declaration that the individual mandate is constitutional or is severable from the remainder of the ACA.

Federal Rulemaking. In 2018, the administration continued to expand access to individual and small group coverage outside the marketplaces, issuing rules that encourage the use of association health plans (AHPs)[1] and short-term, limited duration insurance (STLDI),[2] while taking steps to expand employers' ability to pay for health insurance using health reimbursement arrangements (HRAs).[3] Attorneys General (AGs) from 12 states challenged the AHP rule arguing that it impermissibly reduces consumer protections by aggregating individuals and small groups into large group plans. Meanwhile, because STLDI is not subject to ACA protections, states have moved to more aggressively limit or regulate STLDI under state law. Various organizations are challenging the STLDI rule, arguing that insurance with a term of up to a year that can be renewed for up to three years is neither "short-term" nor of "limited duration."

ACA Waivers. In October 2018, the Centers for Medicare & Medicaid Services (CMS) announced that it would provide broader leeway for Section 1332 waivers of ACA requirements, laying the groundwork for widening differences in the accessibility and affordability of adequate coverage between the states. Section 1332 of the ACA authorizes the federal government to grant "state innovation" waivers of various ACA requirements (now dubbed "State Relief and Empowerment Waivers"). At present, eight states have implemented limited Section 1332 waivers, mostly to secure pass-through funding for reinsurance programs. The new guidance offers significant additional flexibility, allowing states to satisfy Section 1332's equal coverage requirement by making coverage *available*, even if actual enrollment is not equivalent, and by expanding the types of insurance that are considered equivalent to the ACA's offerings to include AHPs and STLDI.[4] In November 2018, CMS endorsed four waiver concepts: (1) an account-based subsidies waiver, which would direct federal subsidies into a defined-contribution, consumer-directed account to pay for premiums or other health care expenses; (2) a state-specific premium assistance waiver, which would use an alternative subsidy structure; (3) an adjusted plan options waiver, which would subsidize additional, off-Exchange plans; and (4) a risk stabilization waiver that increases flexibility around reinsurance programs or high-risk pools. As waivers are granted in 2019, variability in coverage levels across the states may intensify. In addition, judicial challenges to the waiver guidance and particular waivers are likely.

Marketplace Premiums & Enrollment. Early reports show that signups in the federally run Marketplaces are significantly lower in 2019 than they were the year before, even though most consumers shopping for insurance saw *lower* premiums.[5] (This

was particularly true in states that employed a "silver-loading" model to maximize the size of tax credits available to enrollees, thereby offsetting the impact of the administration's non-payment of cost-sharing reductions.) Analysts explained the slowdown in Marketplace enrollment by pointing to the administration's scaled-back outreach and education efforts, the elimination of the individual mandate, and the greater availability of non-Marketplace coverage options, including AHPs and STLDI.

Medicaid Expansion. The group of Medicaid expansion states grew slightly in 2018, with three states—Nebraska, Utah, and Idaho—approving ballot initiatives to expand Medicaid to cover the populations permitted under the ACA. Maine, which approved a similar ballot initiative in 2017 only to have its governor refuse to implement it, elected a Democratic governor who ran on a promise to promptly implement the Medicaid expansion. As discussed in a another Top Ten item, CMS has permitted the introduction of work requirements in a few states, and 2019 likely will bring further legal challenges and experimentation with Medicaid waivers.

Mid-Term Elections. According to exit polls, the most important issue for voters in the 2018 midterm election was health care. The success of ballot initiatives to expand Medicaid in the traditionally Republican states of Nebraska, Utah, and Idaho demonstrates that the politics of health care are changing. Despite the electorate's focus on health care and the decision in *Texas v. Azar,* however, it is uncertain whether we will see significant legislative efforts around health reform from the divided Congress in 2019. Legislative priorities in health care may instead focus on drug pricing (also covered in another Top Ten item), while health reform takes divergent paths in different states and litigation continues. Over the longer term, however, some members of the newly elected Democratic majority in the House of Representatives hope to shift the conversation to more progressive legislation, like the "Medicare for All" bill, which had 123 cosponsors at the time of this writing.

2 Value-Based Payments to Expand in 2019, Regardless of Provider Readiness

—Alexis Finkelberg Bortniker and C. Frederick Geilfuss II, Foley & Lardner LLP

2018 was a slow year for the advancement of alternative payment models. Although we saw the kickoff of the Bundled Payments for Care Initiative Advanced model, the Center for Medicare and Medicaid Innovation (CMMI) was otherwise relatively quiet. In 2019, however, expect a significant acceleration in the implementation of risk-based alternative payment models.

Shortly after Alex Azar became Secretary of the Department of Health and Human Services (HHS) and Seema Verma began her service as Administrator of CMS, it became clear that the two would push to reinvigorate the federal government's move to incorporate value-based payment models. Payment reform has been a hot topic in health care for several years, but prior to their appointments there was a pause in activity under the Trump administration, and the direction that CMS and CMMI would take was unclear. In 2018, Azar and Verma made bold statements about the need to drive change, making it clear that the administration is committed to moving to value-based payments.

Mandatory Payment Programs. On November 8, 2018, Azar announced that CMS plans to unveil new mandatory bundled payment models, one for radiation oncology and two for cardiac care.[6] He noted that the administration is looking to expand mandatory models to other clinical areas, marking a reversal from former HHS Secretary Tom Price's stance that alternative payment models that put providers at risk should be voluntary. Expect to see a push towards mandatory participation for an expanding number of specialties in 2019.

Revamping the Medicare Shared Savings Program. In August 2018, CMS proposed a new direction for accountable care organizations (ACOs) in the Medicare Shared Savings Program (MSSP), with the goal to push ACOs into two-sided risk models more quickly than before.[7] CMS is looking to accelerate the move of ACOs to the two-sided risk model by redesigning the program from the current three-track system to require ACOs to enter in one of two tracks: BASIC or ENHANCED. By eliminating the three-track system, and instead replacing it with a two-track model, CMS is effectively pushing ACOs more quickly from an upside-only model to a true risk-based model in which the ACOs assume some liability for inefficient performance. If the model is finalized, MSSP ACOs will need to decide quickly whether to move into a downside risk model or drop out of the program. The CMS proposal delayed the start of new ACO participants in the MSSP from January 1, 2019 until July 1, 2019.

Quality Payment Program. CMS recently released data under the Quality Payment Program, which implements the Medicare Access and CHIP Reauthorization Act of 2015, indicating positive results.[8] CMS reported that 93% of Merit-based Incentive Payment System (MIPS) eligible clinicians received a positive payment adjustment for their performance. 2019 likely will bring an expansion of Advanced Alternative Payment Models, allowing more providers to move away from MIPS.

In addition to the introduction of new/revamped innovation models, at the end of 2018, CMS issued rules expanding telehealth reimbursement, changing payment models under the Medicare Physician Fee Schedule[9] and creating flexibility in Medicare Advantage benefit design in 2019.[10] These changes are a sign of the direction the administration is headed, and of the likelihood for adoption and implementation of value-based models. As 2019 progresses, we are likely to see an increase in provider-driven, patient-centered models with significant opportunity for innovation. In its renewed commitment to models in which participating providers are required to take downside risk, CMS may be recognizing that the move to value has not occurred at the pace it expected or hoped. Potential reforms to the Anti-Kickback Statute (AKS), Stark Law, and the Health Insurance Portability and Accountability Act (HIPAA) regulations also may help remove barriers to care coordination that many providers cite as reasons for not fully embracing value-based payment models.

3 The Opioid Crisis

—Ashley L. Thomas, Baker Donelson

In 2018, the opioid epidemic dominated news headlines, from government fraud and abuse enforcement activities to a burgeoning body of litigation to rapid legislative developments at the federal and state level. It doesn't appear the opioid epidemic will slip from the headlines in 2019. Data published by the Centers for Disease Control and Prevention's (CDC's) National Center for Health Statistics show that overdose deaths nationwide are still exceedingly high, although the United States did see a decline of overdose deaths in the early months of 2018.[11] Health care providers prescribing opioids and other controlled substances are being scrutinized with greater intensity from state professional licensing boards to federal enforcement agencies and this trend likely will continue in 2019.

In August 2017, the U.S. Attorney General announced the formation of the Opioid Fraud and Abuse Detection Unit, a new DOJ pilot program that utilizes data to identify and prosecute individuals who are contributing to the prescription opioid epidemic. The pilot also funds 12 experienced Assistant U.S. Attorneys in opioid "hot-spots" for a three-year term to focus solely on investigating and prosecuting health care fraud related to prescription opioids. As a result of this initiative, the DOJ is using every tool available to increase prosecution of opioid-related crimes, from criminal prosecutions to issuing the first ever civil injunction under the Controlled Substances Act to prohibit doctors from prescribing opioids.[12] In June 2018, the HHS Office of Inspector General (OIG) and other federal law enforcement agencies participated in the largest health care fraud takedown to date by charging more than 600 defendants with participating in fraud schemes involving $2 billion in losses to Medicare and Medicaid. Since the last takedown in 2017, the OIG also has issued exclusion notices to 587 doctors, nurses, and other providers based on conduct related to opioid diversion and abuse. Data analytics has emerged as a significant tool to help identify opioid-related health care fraud in various "hot spots" around the country allowing DOJ officials to mine federal health care databases and target "outlier" providers who are prescribing opioids at a higher rate than their peers.

The most significant federal legislative development came late in 2018 when President Trump signed into law the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act.[13] The SUPPORT Act was passed with sweeping majorities in the House of Representatives (393-8) and Senate (98-1) and is viewed as an important step in expanding access to addiction treatment. The SUPPORT Act is wide-ranging legislation that touches on almost every aspect of the epidemic including treatment, research, funding, and reporting. In 2019, health care providers will see implementation of some measures included in the SUPPORT Act. Notable provisions of the SUPPORT Act:

- Expand telehealth coverage and reimbursement for treatment of substance use disorders;
- Authorize an alternative payment model demonstration project to increase access to outpatient treatment for Medicare beneficiaries;
- Expand existing programs and create new programs to prevent substance use disorders and overdoses;
- Provide measures to prevent illicit flow of opioids into the United States by mail; and
- Provide funding to encourage research and development of new non-addictive painkillers and non-opioid drugs and treatments.

According to the National Conference of State Legislatures, as of October 2018, 33 states have enacted legislation that provides guidance or limitations on opioid prescriptions.[14] Most states have enacted legislation that limits first-time opioid prescriptions to a specific supply. A seven-day prescription limit is the most common, which aligns with the recommendations the CDC established in 2016. However, some states do provide exceptions. Arizona allows health care providers to administer an initial opioid prescription for a supply of 14 days following a surgical procedure,[15] while North Carolina allows up to seven days for post-operative relief.[16] In March 2018, Florida became the first state to impose a three-day limit on opioid prescriptions. In Maryland, providers must prescribe the lowest effective dose of an opioid for a quantity that is not greater than that needed for the expected duration of pain.[17] In addition to states, several pharmacy benefit managers and pharmacies, including CVS and Walmart, have adopted limitations for first-time opioid prescriptions.

4 Fraud and Abuse Outlook

—Tony Maida, McDermott Will & Emery LLP

The fraud and abuse landscape in 2019 should continue to be a crowded one, with the implementation of DOJ's new policies, continued interpretation of the *Escobar* decision, expanded use of the False Claims Act (FCA) in health care enforcement, new fraud and abuse laws, and HHS activity.

DOJ Policy Evolution. In 2019, expect DOJ to continue acting on enforcement policies expressed in the Granston and Yates Memos, as codified in the revised Justice Manual.[18] The Granston and Yates Memos respectively outlined the circumstances where DOJ should seek dismissal of qui tam[19] FCA cases under the statute's dismissal provision,[20] and when DOJ gives companies "cooperation credit" and seeks to identify and hold accountable "culpable individuals." In the year since the Granston Memo's publication, we have seen several cases where DOJ has affirmatively moved to dismiss the relator's case and an emerging circuit split on the standard courts apply. The Yates Memo has been with us for a few years now, continues to be evident in DOJ's pursuit of individuals, and remains in the Justice Manual, despite criticism from the defense bar about the lack of clarity on how corporate "cooperation credit" applies in the civil context. Based on Mr. Granston's statements at a recent conference, expect some additional clarity on this issue in 2019.

One remaining question following the revised Justice Manual is the continued relevance of the Brand Memo, which instructed prosecutors to not use noncompliance with agency guidance documents as the basis for proving violations of applicable laws in affirmative civil action cases. The Brand Memo was not incorporated into the Justice Manual revision, but it was not contradicted or repudiated either.

Expansion of Targets Beyond Traditional Providers. For a long time now, many sectors of the health care industry have become accustomed to being subject to FCA actions, whether brought by relators or DOJ affirmatively. But these sectors mostly are composed of traditional health care providers or suppliers that directly deliver patient care and submit claims to Medicare for such services. DOJ and relators have begun extending their reach to other sectors of the health care industry, such as Medicare Advantage plans, electronic health record companies, and private equity owners.[21] Some of these efforts have resulted in large settlements (in the case of eClinicalWorks[22]), but otherwise these cases are in an investigative or litigation stage. On a related note, the U.S. District Court for the District of Columbia vacated the Medicare Part C overpayment rule, which may call into question the government's theories concerning managed care FCA liability.[23]

Post-Escobar Litigation. Since the Supreme Court's decision almost three years ago, tracking the jurisprudential development of *Escobar*[24] is a perennial topic for this Top Ten section. For 2019, expect continued litigation on the lower courts' interpretation of the two-part implied certification theory test and whether the allegations or evidence of materiality are sufficient to pass muster under any FCA theory.

Escalating Enforcement Efforts to Address the Opioid Epidemic. The government has significantly increased its enforcement efforts to combat the opioid crisis, including adding prosecutorial resources and deeper coordination among the relevant agencies to pursue criminal and civil cases against prescribers, pharmacies, and others in the drug supply chain. These efforts, which are discussed in another section of the Top Ten, are an area to expect increased enforcement focus over the next year.

De-Regulatory Sprint. In 2018, HHS took the most definitive step in recent memory to address the obstacles the federal AKS and the Stark Law pose to care coordination among different, independent providers that the industry has long lamented. True to its name, the *Regulatory Sprint to Coordinated Care* is focused on advancing HHS' stated desire to move the Medicare program to a value-based payment model away from fee-for-service. However, HHS also solicited comments more broadly on how the AKS and Stark Law present problems for the industry. If HHS moves to address these problems, it could provide welcome relief from non-meritorious claims under the FCA. Expect to see proposed rules on AKS and Stark regulatory reform in 2019.

New F&A Laws for Recovery Homes, Treatment Facilities, and Labs. While HHS moved in the de-regulatory direction, Congress created a new fraud and abuse law that could have substantial unintended consequences. In Section 8122 of the recently enacted opioid legislation, Congress created the Eliminating Kickbacks in Recovery Act (EKRA), a commercial payer-focused kickback statute that applies to recovery homes, clinical treatment facilities, and laboratories. While the law appears to be Congress' attempt to fill a gap in federal law regarding patient brokering activities associated with treatment and recovery efforts, it contains a number of unclear provisions and is not in all respects limited to patient brokering or substance abuse providers. Further, DOJ is the agency charged with issuing regulations implementing the EKRA, not the OIG. It remains to be seen whether Congress will make adjustments to the statute in response to industry concerns or whether DOJ will issue prosecutorial guidance to provide comfort that traditional and legitimate business activities would not be subject to prosecution.

CMS Program Integrity Activity. Government enforcement activity is no longer limited to DOJ and OIG actions. CMS has steadily increased its own activities in this area, including suspension and revocation actions following the expansion of the agency's regulations in 2015. These actions have been taken based on billing issues as well as for enrollment reasons. On the contractor front, 2018 is the first year of the fully implemented Medicare Administrative Contractor "Targeted Probe and Educate" process and a reorganized program integrity contractor (good-bye "Zone" and hello "Unified") and Recovery Act Contractor functions. Expect to see these contractors continue to ramp up their activities.

5 Technology Innovation Continues to Outpace the Law

—Alaap B. Shah, Epstein Becker & Green PC

The pace of information technology innovation in the health care industry continues to increase, yet the law has had difficulty keeping pace. This often leaves the legal profession struggling to fit a square peg into a round hole. The law likely will face even more challenges in 2019 as interest and spending on health information technology innovation continue to rise. While there are a cornucopia of technological and data science advancements occurring simultaneously, there are a couple to watch closely in the year ahead.

Artificial Intelligence. Artificial Intelligence (AI) is still an emerging field, but rapidly maturing. AI technologies are entering the market and seek to create efficiencies, cut costs, and improve quality and safety. The potential value of AI is promising, but the health care industry will grapple with questions about responsible use of AI. Further, few laws directly address the use or development of AI. As such, the legal profession is left to creatively apply existing laws and regulations to AI paradigms. Analysis of AI will need to return to the touchstones of ethics and policy to inform the debate. Lawmakers

also will struggle to develop standards to govern AI without stifling innovation. Accordingly, lawmakers will likely seek to strike the right balance between regulating development and use from a premarket and postmarket perspective.

A common theme that has and will continue to drive the dialogue relates to ensuring that AI technologies are not developed as "black boxes." It will be hard to trust what we cannot truly understand. Managing legal risk will require evaluating AI tools based on transparency of algorithms, reliability of outputs, accountability features, and safeguards around privacy, security, and safety. While the law gets sorted out, early adopters of AI technology will be left to allocate risk through contracts with developers, partners, and third parties leveraging AI technology.

Cybersecurity Risk and the Internet of Things. Two trends are clear moving into 2019. First, data will increasingly be digital and health information technology will be decentralized further. Second, cybersecurity risk will simultaneously grow.

Many health care entities have embraced the Internet of Things (IoT) as new devices and systems are incorporated into networks on a daily basis. Unfortunately, many IoT environments have developed through organic, ad hoc approaches without a unified risk management strategy in place. As such, these IoT environments have essentially created ticking time bombs in the form of growing cybersecurity risk. These risks will continue to increase because the same things that make IoT advantageous make IoT problematic from a security perspective. Health care entities should continue to worry about ransomware and other malware infiltrating their networks and adopt enterprise-wide risk management frameworks to reduce risk associated with cyber threats and IoT.

Although the law lags behind on these issues, the Food and Drug Administration (FDA)[25] and other agencies[26] have expressed concerns about cybersecurity in the health care industry. However, this is leading to a confusing jumble of viewpoints, jurisdictions, and standards that entities (and their legal counsel) will need to navigate to effectively manage risk moving forward. Indeed, there is a need for more unification in how to manage these risks while continuing to allow for innovation. Will 2019 be the year we see greater clarity and harmonization?

6 Drug Pricing and Transparency

—AHLA

Skyrocketing prescription drug prices continue to make headlines and draw scrutiny from federal and state lawmakers looking to rein in health care spending and out-of-pocket costs for consumers. At the federal level, the acute interest in drug pricing and transparency has not culminated in much legislation so far, although Congress did pass a measure in 2018 banning private health insurers and Medicare plans from using "gag clauses," which restrict pharmacists from telling consumers if their prescription would cost less by paying for it out of pocket rather than using their insurance plan.[27]

Administrative Efforts. In his 2018 State of the Union Address, President Trump cited lowering prescription drug prices as one of his top priorities. To that end, the administration rolled out its American Patients First blueprint,[28] with the stated goals of improving competition, lowering out-of-pocket costs, enhancing negotiation, and evaluating incentives for lower list prices. Since then, HHS and the FDA have been busy implementing the administration's agenda for lowering drug costs.

CMS' activity in 2018 included proposing to align more closely what Medicare Part B pays for "select" physician-administrated drugs with international prices[29] and allowing Medicare Advantage plans to use "step therapy" for Part B drugs.[30] Part B drugs, which include those used to treat cancer, rheumatoid arthritis, and multiple sclerosis, often are among the costliest. CMS also has taken aim at drug prices in Medicare Part D. In August, the agency reversed course and said it will allow Medicare Part D plans to tailor their formularies by drug indication (known as indication-based formulary design).[31] Under a recent proposed rule, a Part D sponsor could exclude a protected class drug from its formulary if the price of the drug increased beyond a certain threshold.[32]

The administration unveiled in October 2018 a controversial proposal that would require pharmaceutical manufacturers to include a drug's list price in direct-to-consumer (DTC) television advertisements.[33] Companies currently must only disclose a drug's major side effects in advertisements. The Pharmaceutical Research and Manufacturers of America indicated it may initiate a legal challenge if the administration finalizes the proposal to require a drug's list price in DTC television ads. Many of the administration's efforts have drawn fire from the pharmaceutical industry and raised concerns about the potential for negatively affecting patient access to drugs they need.

The FDA also has taken a number of steps to lower drug prices, including releasing draft guidance outlining how to make more drugs used to treat certain common or chronic conditions available to consumers without a prescription.[34] The agency said it plans to issue a proposed rule in February 2019 to help clarify how drug manufacturers could market certain products as nonprescription. The agency also announced it was establishing a work group to examine drug importation from other countries under "narrow conditions." The move attracted widespread attention because of the FDA's long-standing opposition to drug importation based on safety concerns. The agency also unveiled a Biosimilar Action Plan for promoting competition from biosimilars of expensive biologics used to treat many life-threatening diseases like cancer and autoimmune conditions.

Administration officials have repeatedly zeroed in on rebates as a driver of higher list prices and have said they plan to reexamine the safe harbor for drug rebates under the AKS. In July 2018, the Office of Management and Budget received for review a proposed rule entitled "Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection," signaling the administration is considering changes in this area, which could have significant repercussions across the pharmaceutical industry and drug supply chain.

Legislative Activity. Despite bipartisan agreement that drug prices are too high, lawmakers remain divided over how to bring them down. Democrats, who will be assuming the majority in the House of Representatives in January 2019, continue to push for the federal government to negotiate Medicare Part D drug prices, a move Republicans strongly oppose. Expect lawmakers in 2019 to continue their focus on drug pricing. Whether that focus results in meaningful legislation remains to be seen.

State Efforts. State legislators also are moving to combat excessive price increases. Maryland, for example, enacted a law taking aim at "price gouging" in the sale of essential off-patent or generic drugs, giving the state attorney general authority to sue drug manufacturers for violating the statute. However, in April 2018, the Fourth Circuit found the law violated the dormant Commerce Clause because it regulated the price of transactions outside of Maryland.[35] Maryland Attorney General Brian Frosh recently asked the Supreme Court to review the decision, which could be significant for similar legislation in other states. In August, a federal court in California dismissed on standing grounds a challenge to a California law enacted in 2017 that requires drug manufacturers to give public notice before hiking prices above a certain level.[36] The Vermont legislature overwhelmingly approved a measure that would allow drug importation from Canada. Although the state's governor signed the bill into law, importation proposals would need federal approval to go forward.

For 2019, the pace of activity in the effort to lower drug prices is unlikely to slow. Even if Congress is unable to move legislation at the federal level, it seems the administration and the states will continue to focus on this issue.

7 Disruptor and Disruption

—Gary Scott Davis, McDermott Will & Emery LLP

Following the passage of the ACA, capital was readily available to fund health care start-ups.[37] Many among a once-eager wave of start-ups determined to disrupt the health care industry fizzled out or found niche markets where they are able to offer services to a larger company.[38] Most were not prepared or able to compete in the highly regulated health market against well-established companies.[39] In spite of these and other challenges, health care start-ups continue to attract millions in venture capital each year.[40]

In 2019 disruptors will again seek to reform the health care marketplace through new structures and services. Driving these disruptors are a focus on technology and the consumer experience. By utilizing technology, disruptors hope to drive down costs by rooting out systemic inefficiencies and engaging with customers to make them feel more empowered and involved in managing their own health.[41]

Why is health care such a hot segment for disruptors and disruption? It has all of the attributes of an industry ripe for disruption—highly regulated, pricing opacity (value or costs or access), and consumer dissatisfaction.[42] In regard to this third attribute, two cohorts within this population have increasingly become the focus of many disruptors—Millennials and Baby Boomers. For Millennials, convenience is key and they have cut their proverbial teeth on FinTech,[43] which could become a clarion call to the health care industry. And Baby Boomers consist of a large number of persons who are both economically secure and tech savvy.

What do disruptors have in common? They view the current way of doing business as "disorganized care" and seek to redefine it as more "organized care." In the traditional market place, consumers often must navigate separate websites—a series of "digital walled gardens"—to access their data, contributing to the perception that the health care market is confusing and non-consumer friendly.[44] Disruptors look at the current consumer experience and seek improvement. To them health care is something that is "done with" the patient/consumer rather than something that is "done to" the patient/consumer. They act as differentiators, creating a sense of membership or belonging, simplification, and value creation. This is accomplished in part with technology[45] and a greater focus on the consumer as an individual.

There is likely no better role model for the health care disruptor than Amazon. Starting out as a disruptor in the book industry doing business from its founder's garage, it has effectively redefined the entire retail industry. Its success as a disruptor can be traced to its focus on the consumer and the consumer's experience, its treasure trove of data about its customers, having created a sense of community or membership (a/k/a Prime), price competitiveness, and convenience. Over time, Amazon has developed and honed its ability to anticipate consumer needs, manage the supply chain, eliminate waste, and control costs and expenses. It possesses much of the necessary groundwork to launch one or more successful health care ventures. It has already mastered the efficient collection of data on consumer spending habits, and it could potentially use that data in innovative ways to discern the decision-making process of a health care consumer.[46]

Amazon, JP Morgan Chase, and Berkshire Hathaway have joined together to focus on the health insurance/benefits segment of the industry. Although none of the three companies has direct experience in this space, their announcement sent health stocks reeling and put added pressure on major legacy health care companies.[47] In May 2018, JPMorgan Chase CEO Jamie Dimon laid out six issues that the venture's new management team would focus on, including aligning incentives, studying the high cost of waste, administration, and fraud, empowering employees to make better choices, developing better wellness programs, evaluating the over- and under-utilization of specialized medical procedures and pharmaceuticals, and examining the high cost of end-of-life care.[48] As with others that have focused on disrupting this industry segment, among the attributes that can be expected of their initiative are: consumer (end-user) focus and engagement, relationship building, simplification, and personalization through an emphasis on design and user-friendliness in apps and websites.

Two tools that are expected to fuel continuing disruption in the health care industry are AI and blockchain. Approximately 86% of health care provider organizations are presently using some form of AI technology.[49] Learning algorithms can process

large quantities of data, which will have effects on diagnostics, imaging, preventive and predictive medicine, and clinical decision making. Apple has acquired several AI firms, and Google's DeepMind and Verily subsidiaries are working on creating AI tools for physicians and diagnostics.[50] Amazon is reportedly developing its voice assistant Alexa's capabilities to respond to health care inquires.[51] Google is looking into using Google Home to provide information on minor ailments, managing chronic conditions, and searching for physicians.[52]

Blockchain is an open, decentralized ledger that records transactions in a way that is both secure and independently verifiable.[53] Rather than saving information on servers, information is distributed between "nodes," which each act as a replicated database that distributes data to other nodes and adds transaction information to the ledger.[54] Transaction information, known as "block data," is secured on the blockchain through cryptography, and participants use individual network keys, which act as digital signatures to add block data and validate records.[55] This secure, open, and verifiable ledger can be leveraged to break down barriers across the health care continuum thereby improving the ultimate consumer experience.

Disruptors will likely continue to focus on the delivery of services outside of hospitals and physician offices (e.g. retail clinics, telemedicine). Availability and accessibility will be cornerstones including 24/7 accessibility, scheduling through an app, and remote monitoring. These market disruptions are intended to position the patient, not the provider, at the center of health care delivery. It is a new paradigm, one that is more convenient, easier to use, and less expensive for consumers. The competitive challenge for legacy participants will be how to meet patients and consumers where, when, and how they want to receive care and services.

Where the disruptors and disruption will lead to in 2019 is an unknown. Both newcomers and current customer-centric companies, each with a focus on delivering convenience and value, may find themselves emerging as the new preferred vendors of health care services. Legacy participants in the health industry will need to remember that in the end consumers, not companies, disrupt industries. When a company builds a compelling customer experience and service offering, the consumer wants to use it over and over again. Continued success in the evolving health industry will likely require legacy participants to become "consumer-obsessed." More decisions will be at the consumer/patient level, with information and content presentation driving both disruptor success and continued legacy relevance and competitiveness. A relentless focus on anticipating and delivering on the needs and preferences of current and potential consumers will be critical to becoming competitive or staying relevant in the rapidly evolving health care industry.

8 Medicaid Work Requirements

—Jennifer Evans and Ryan Thurber, Polsinelli

Two years ago, CMS announced a new willingness to increase state-level control and direction over their Medicaid programs, including the introduction of new Medicaid waivers.[56] Among a wide range of waivers, a number of states have sought to implement new standards for Medicaid eligibility that can be broadly described as Medicaid "work requirements."

As of this writing, five states have obtained CMS approval for Medicaid work requirements, and an additional nine states have submitted waiver applications to introduce work requirements to their Medicaid programs.[57] In Kentucky, a federal court blocked the approval and implementation of these requirements and remanded to the agency for further review. CMS reopened the public comment period on the state's demonstration proposal and recently reapproved the state's waiver application with the work requirements.

Work Requirement Overview. Work requirements are generally designed to encourage (or require) certain Medicaid beneficiaries to engage in or actively seek gainful employment as a condition of Medicaid eligibility. Proponents of work requirements tout increased health and economic benefits, as well as increased independence for beneficiaries.[58] Approved work requirement programs include:

- Indiana received approval to modify Healthy Indiana Plan to include new "community engagement" requirements.[59] These requirements include employment, education, job skills training, or volunteer work, up to a maximum of 20 hours per week.[60]
- New Hampshire received approval for a new premium assistance model for adult (i.e., ages 19-64) Medicaid beneficiaries to require 100 hours/month of eligible community engagement, including employment, education, and community service.[61]

Work requirements apply only to specific groups of Medicaid beneficiaries.[62] Penalties for noncompliance vary, but include suspended or discontinued Medicaid eligibility. In Arkansas, for example, 4,353 people lost eligibility for Medicaid coverage during the first three months.[63] These Arkansas beneficiaries are ineligible for Medicaid coverage for the remainder of 2018, unless they qualify for an exemption.[64]

Implementation of work requirements has attracted legal challenges from consumer protection and health care advocacy groups, who view work requirements as a thinly veiled excuse to remove otherwise eligible beneficiaries from Medicaid rolls. In June, a federal judge sided with Kentucky beneficiaries, finding that CMS' approval of Kentucky's work requirements was arbitrary and capricious.[65] That challenge will likely continue now that CMS has once again approved Kentucky's work requirements. Challenges to other states' work requirements also are expected.

Impact on Providers. Medicaid work requirements impact health care providers by diminishing the number of people eligible for Medicaid coverage and increasing uncompensated care. Implementation of work requirements and subsequent legal challenges may have other, unintended consequences as states adapt to legal developments and operational challenges.

In Kentucky, Governor Bevin threatened to end Medicaid expansion if the ongoing legal challenge to Kentucky's work requirement ultimately prevails.[66] Consequently, providers should be aware of both ongoing updates to work requirements

across the country, and the unintended impacts these waivers and subsequent legal challenges may have on eligibility and the overall Medicaid program.

9 Behavioral Health Issues

—Gerald (Jud) E. DeLoss, Greensfelder Hemker & Gale PC

The upcoming year promises to see continued activity in the behavioral health (mental health and substance use disorder) field as the opioid crisis and integration of behavioral health and physical health remain at the forefront of health care.

One of the more interesting changes that came about towards the end of 2018 was CMS announcing action to address a long-standing prohibition under Medicaid that was considered a barrier to substance use disorder (SUD) treatment. Historically, the institutions for mental disease (IMD) exclusion prohibited the use of Medicaid federal financial participation (FFP) for care provided to most patients in mental health and SUD residential/inpatient treatment facilities larger than 16 beds. The exclusion applies to all Medicaid beneficiaries under 65, except for payments for inpatient psychiatric services provided to those under age 21. The IMD exclusion was originally crafted to place the burden of payment for residential/inpatient settings at larger institutions and facilities on the states, particularly in light of what many felt was the "warehousing" of patients with mental health and SUD conditions rather than the provision of treatment. CMS would permit FFP for services to enrollees with opioid-use or cocaine-use disorders up to 30 days in a 12-month period. States must include specified information in their applications, including plans to improve access to outpatient care. 2019 should see the implementation of the SUD treatment exception to the IMD exclusion and an expansion of the exception. Already CMS has issued a letter to State Medicaid Directors identifying an additional exception to the exclusion for the provision of mental health treatment in the IMD setting.[67]

The CMS letter to State Medicaid Directors announced opportunities for states to address the need for treatment of adults with serious mental illness (SMI) or children with serious emotional disturbances (SED). Many of the opportunities were previously announced or available to states through other programs and initiatives. The biggest change announced was the ability for states to implement a demonstration project under Section 1115(a) to provide Medicaid FFP for mental health services to beneficiaries in IMDs. Under a CMS approved demonstration, FFP would be available for services for beneficiaries who are short-term residents in an IMD primarily to receive mental health treatment. The proposal is similar in most regards to the demonstration available for states to treat beneficiaries with SUDs in an IMD. States may participate in both the SMI/SED and the SUD demonstrations simultaneously. Any individual receiving SMI/SED treatment in an IMD must also be screened for any co-occurring SUD or physical health condition. Similar to the SUD demonstration, the time in residential treatment would be limited on average to 30 days. Further, as with the SUD demonstration, FFP for room and board is not available and must not negatively impact community-based mental health care. The demonstration proposal is not available for nursing homes or for inmates confined involuntarily under criminal law. The demonstration must be budget neutral, although the letter sets forth considerations for obtaining budget neutrality that are beneficial when considering all factors for neutrality. The goals, milestones, and other details in the letter are similar, if not identical, to those for the SUD IMD demonstration.

CMS also recently published proposed changes to the Medicaid Managed Care regulations.[68] CMS is proposing modifications to the regulations that were substantially overhauled in 2016. Among the proposed revisions are changes to:

- Coordination of benefits agreements among Medicaid managed care organizations (MCOs);
- Certification of rate ranges;
- Ability of states to approve directed payments to providers;
- Additional guidance CMS must issue annually on capitation;
- Tweaks to the medical loss ratio;
- Interpreter requirements for non-English speaking patients;
- Reliance upon MCO grievance processes before engaging in state processes relating to disenrollment;
- Network adequacy no longer based solely upon time and distance but a variety of quantitative standards, such as: minimum provider-to-enrollee ratios, a minimum percentage of providers accepting new patients, or maximum wait times for an appointment; and
- Quality rating and review systems.

One item that was not included in recent federal legislation passed by the Senate was anticipated modifications to the federal law governing the confidentiality of SUD information at federally assisted treatment programs.[69] This law is generally referenced by the corresponding regulation: 42 C.F.R. Part 2. These rules have been heavily criticized as a barrier to effective treatment and coordination of care because they impose stringent consent requirements for the disclosure of SUD information for most purposes, including treatment, payment, and health care operations that HIPAA would permit without consent or authorization, as well as a prohibition on re-disclosure that requires separate consent each time a recipient desires to disclose the received SUD information to another party. The Overdose Prevention and Patient Safety Act,[70] which passed in the House only, would have permitted the disclosure of SUD information without consent to HIPAA-covered entities and other federally assisted programs for purposes of treatment, payment, and health care operations. The Act also added anti-discrimination protections and prohibitions on the use of SUD information in criminal, civil, or administrative proceedings. Further, it would apply HIPAA's breach notification requirements on federally assisted SUD treatment programs. Despite its omission from the final Senate opioid legislation, many consider revisions to the statute and/or regulations to

be possible in the near future. The Substance Abuse and Mental Health Services Administration has announced further revisions (in addition to those made in 2017 and 2018) to the regulations to remove barriers to coordinated care and to permit sharing of information among providers and programs.[71] The form of the final revisions, if any, remains to be seen.

SUD and mental health treatment and those that provide these services are expected to see continued support to address these critical public health crises. Heightened recognition due to the opioid epidemic has been a bittersweet warning about the need for adequate funding, support, and integration for the behavioral health field.

10 Private Equity Investment in Health Care

—Michael F. Schaff & Grace Mack, Wilentz Goldman & Spitzer PA

Increased PE Interest After Enactment of the Affordable Care Act. Since the enactment of the ACA, private equity companies have increasingly become interested in the health care field. In 2019, we expect the influx of private equity investment in health care to continue and expand. Private equity companies see value in health care and provide the capital needed by practices to implement data analytics and population health management tools that help to reduce costs and increase efficiency. This is coupled with physicians' frustration with the ever-expanding administrative duties of running a practice and the desire to focus on the practice of medicine.

Beware of State Law Restrictions. There are a number of significant regulatory hurdles that need to be cleared in private equity investments in health care, including state laws on the corporate practice of medicine prohibitions, fee-splitting restrictions, licensure laws, state insurance laws, and antitrust concerns.

In particular, the corporate practice of medicine (CPOM) doctrine should not be ignored. The CPOM has become more and more important in structuring transactions with private equity firms. This analysis is state specific. In CPOM states, the CPOM doctrine generally prohibits a business entity such as a private equity investor from practicing medicine or employing a physician. Thus, the business people form a management services organization (MSO) and provide space, equipment, non-clinical personnel, supplies, and management services to the medical practice. An MSO is set up as either an LLC or corporation that is owned in whole or in part by the private equity investor or its affiliate, separate from the medical practice itself. The MSO is paid a fee for providing non-clinical services to the medical practice. The fee should be fair market value and commercially reasonable for the services provided.

Management arrangements need to be carefully analyzed to ensure that these transactions are properly structured. In CPOM states, it is essential that the MSO not interfere with the professional's medical (clinical) judgment or otherwise exert control over the medical aspects of the medical practice. In certain CPOM states, such as New Jersey, the medical practice must be owned entirely by licensed professionals.

As these management arrangements become more common, we expect regulation and enforcement to become more common as well. Recently, state courts and attorneys general have been focusing on compliance with CPOM laws. In *Allstate Ins. Co. v. Northfield Medical Center, P.C.*,[72] the New Jersey Supreme Court ruled that an MSO was the practical owner of the practice and thus the structure violated the New Jersey CPOM. *In the Matter of Andrew Carothers, M.D., P.C.*,[73] a New York court held that a non-physician owned entity was engaged in the corporate practice of medicine.

One area of active investment by private equity firms is dental practice management. Many states have corporate practice of dentistry restrictions similar or more restrictive than CPOM. As a result, there has been increased focus on arrangements with dental practice MSOs.

Trend: R&W Insurance. As a result of the increase in private equity transactions and the nature of the health care industry, it is becoming more common to see requirements for obtaining representation & warranty (R&W) insurance to absorb some or all of the risk of the investment, allowing the parties to assume less risk than under traditional indemnification provisions. We expect this trend to continue and evolve requiring negotiation as to the responsibility and scope of the indemnification provisions.

Targeted Sectors and Specialties—Who Will Be Next? Initially, there was a tremendous amount of interest by private equity investors in hospitals, ambulatory surgical centers, and outpatient facility-based specialties such as anesthesia, radiology, emergency services, and hospitalists. As noted earlier, there also has been significant activity in the dental practice arena. In addition, retail medicine, dermatology, ophthalmology, pain management, urology, ob/gyn, disease-state specialties (gastro, orthopedics), and primary care services also have been an active area. Private equity investors are also moving beyond professional services and targeting health-related investments such as lab and toxicology companies, health information technology companies, behavioral health, and revenue cycle and back office services.

What will be the sectors or specialties on the radar of private equity in 2019? As the private equity firms gain experience in the health care field, we expect to see continued interest in the specialties already in play with an expansion into related fields. We also anticipate that the increase in data analytics and telehealth capabilities will affect the types of future investments. We caution that the private equity arrangements must be structured to comply with the applicable laws and preserve the autonomy of the physicians and dentists with respect to the practice of their professions. C

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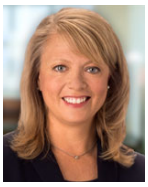

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61 These community engagement requirements will be effective no sooner than January 1, 2019; *see* New Hampshire Health Protection Program Premium Assistance, § X (May 7, 2018), https://www.dhhs.nh.gov/pap-1115-waiver/documents/nh-pap-stcs-05072018.pdf.

62 Indiana, for example, excludes pregnant women, medically frail beneficiaries, students, some caregivers, and beneficiaries in active SUD treatment.

63 This represents approximately 9% of Medicaid beneficiaries to whom the Arkansas work requirements apply. Arkansas Dep't of Human Servs., *Coverage Closures for Arkansas Works Recipients Who Did Not Meet Work & Community Engagement Requirement for Three Months* (Sept. 12, 2018), https://humanservices.arkansas.gov/newsroom/details/coverage-closures-for-arkansas-works-recipients-who-did-not-meet-work-requi.

64 E.g., exemption based on pregnancy or disability.

65 *Stewart v. Azar*, 313 F. Supp. 3d 237 (D.D.C. 2018).

66 Matthew G. Bevin, Governor, Executive Order 2018-040, Relating to Medicaid Expansion (Jan. 12, 2018), http://apps.sos.ky.gov/Executive/Journal/execjournalimages/2018-MISC-2018-0040-253682.pdf. Governor Bevin also cut vision and dental benefits in response to the negative ruling, but these benefits were later restored. Jack Brammer and Daniel Desrochers, *In a surprise move, state restores dental, vision coverage for Medicaid Recipients*, Lexington Herald Leader, July 19, 2018, https://www.kentucky.com/news/politics- government/article215195900.html (last visited Nov. 13, 2018).

67 CMS Letter to State Medicaid Directors SMD # 18-011, RE: Opportunities to Design Innovative Service Delivery Systems for Adults with a Serious Mental Illness or Children with a Serious Emotional Disturbance.

68 83 Fed. Reg. 57264 (Nov. 14, 2018).

69 42 U.S.C. § 290dd-2.

70 H.R. 6082 (2018).

71 RIN 0930-AA32 (Oct. 17, 2018).

72 228 N.J. 596 (2017).

73 No. 2013-10969, 2017 WL 1240262 (N.Y. App. Div. Apr. 5, 2017).