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AFTER THE CURVE

An analysis of the changing face of healthcare

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INTRODUCTION

In the same way that the events of September 11, 2001, suddenly and permanently changed the way we travel, the current Coronavirus (COVID-19) pandemic is suddenly and permanently changing the way we deliver, consume and pay for healthcare services in the United States. Over the last few decades, we have struggled to find policy or market-based solutions to increase clinical quality while also reducing overall costs. Now, the COVID-19 pandemic has exposed additional systemic weaknesses in our fragmented, episodic approach to healthcare delivery and historical undervaluing of preventative and public health measures. The pandemic has also opened doors to innovation, however, as industry participants mobilize crisis resources; adjust operations for enhanced screening, sanitization and social distancing measures; and harness telehealth capabilities to deliver healthcare remotely. For as much talk as there has been about "innovative disruption" in recent years, Mother Nature has proven to be a more effective disruptor and agent of change.

As communities begin to reopen, COVID-19 remains a virulent threat. While scientists race to develop a vaccine, most acknowledge that a "return to normalcy" will be a long process. Indeed, some things will never again be the way they once were. In the following pages, we highlight the challenges and opportunities that healthcare operators and investors should consider as the industry finds its way to a new normal.

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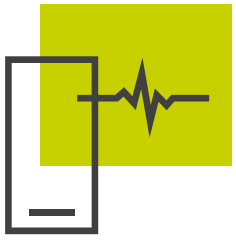
DIGITAL HEALTH

Telehealth and Remote Care Are Here to Stay

Telehealth adoption rates exploded in recent months as healthcare providers rushed to leverage this solution to care for patients while complying with stay at home orders and social distancing requirements. Healthcare providers have largely set aside the long-running debate over whether telehealth allows for quality patient care, and states and federal governments have knocked down long-standing obstacles to adoption and use, including antiquated licensure and reimbursement policies, for the duration of the public health emergency. Some key takeaways:

> Expect to see the continued integration of artificial intelligence systems into telehealth services to deliver more efficient care.

- The Coronavirus Aid, Relief, and Economic Security (CARES) Act and subsequent actions greatly supported the use of telehealth services by lowering long-standing barriers to Medicare reimbursement and acknowledging the central role that telehealth plays in coordinated care delivery.
- The Centers for Medicare and Medicaid Services (CMS) changed its Medicare payment requirements to allow traditional Medicare beneficiaries to access telehealth services from home, with reimbursement on par with amounts paid for in-person medical services.



- The Office of Civil Rights, the US Drug Enforcement Administration and other agencies loosened restrictions to allow providers to use technology to deliver telehealth services.
- State emergency declarations and orders are aimed at expanding Medicaid coverage and easing licensure barriers.
- The increased utilization of telehealth services is likely to be self-reinforcing, as patients adapt to new modalities for care delivery and payors appreciate the cost savings of treatment outside of the acute care setting.

Regulators have already signaled that some of the changes made during the public health emergency may become permanent. If there is a silver lining to the COVID-19 pandemic, it is that the circumstantial need for telehealth services has given regulators empirical evidence that, generally speaking, the practical benefits far outweigh the risks that previously drove regulatory limitations. Moreover, regulatory innovation may be an inevitable need as more consumers become facile with telehealth and grow to appreciate the efficiency and convenience that remote services afford. Indeed, for higher-risk patient populations, telehealth may emerge as the preferred modality.

Changing attitudes toward telehealth services will continue to spur innovation. For example, we anticipate better integration of telehealth services in skilled nursing facilities, nursing homes, and assisted living and independent living facilities, as infection control will remain an important focus for quite some time. Looking past the COVID-19 pandemic, we also anticipate the continued integration of artificial intelligence systems into telehealth services to deliver more efficient care, help manage chronic conditions with remote patient monitoring and home-based sensors, and better coordinate the care of patients with multiple diseases and various specialists.

Implementation of Digital Tools to Speed Care and Improve Outcomes

Prior to the COVID-19 pandemic, the healthcare system was largely centered on in-person provider-patient visits. Even so, health systems, health plans and other stakeholders eagerly sought innovative and elegant digital health tools to better manage the allocation of healthcare resources, monitor and coordinate care between in-person visits, and assist healthcare providers and patients in making healthcare decisions. The pandemic underscored the urgent need for such tools and has increased provider and patient comfort in using digital technologies for healthcare delivery.

This momentum will continue, particularly with increased use of remote monitoring, clinical decision support software (bringing real-time, curated data into the hands of clinicians and consumers), and supplemental patient engagement apps and tools that move beyond an episodic care delivery model to an enhanced continuum of care. Digital health innovation will need to assist providers with making real-time healthcare recommendations and improving patient adherence and follow-through on those recommendations. Digital tools also promise to equip stakeholders with additional resources to manage chronic conditions, enhance preventative care, accelerate recovery, and create additional connective interactions between providers and patients.

Beyond enhancing the patient-provider interface, technological tools also present new pathways for rapid data aggregation and analysis. These capabilities should allow providers to develop smarter treatment plans adapted to particular patients and conditions, with technological interfaces that empower clinicians and patients to form a partnership for care delivery and management. That information and the associated outcomes will in turn provide empirical support for new payment models that can truly be outcomes-based.

> The 21st Century Cures Act has helped broaden efforts to ensure more effective communication among patients, providers and health plans.

Data Readiness: The Healthcare System of the Future Depends on It

All of these innovations are dependent upon more complete, structured data that can move seamlessly among healthcare practitioners, with the patient at the center. For many years, government task forces and committees have worked to enhance data standards and multi-party connectivity. The 21st Century Cures

Act advanced those efforts to promote more effective communication among patients, providers and health plans through the use of interoperable systems. These regulatory pushes had momentum pre-COVID-19, but were slowed by the health crisis just when they were most needed.

Moreover, the pandemic itself highlighted what many have known for years: despite valiant efforts by many stakeholders, our digital health infrastructure lacks the scale and integration necessary to obtain, harness and analyze data in real time across multiple players, including public health authorities. Challenges with broad-based testing and contact tracing during the COVID-19 pandemic exemplified how our disease identification and prevention systems were immature and insufficient. The real opportunity, however, is much broader. A new-found interconnectivity would allow industry stakeholders to identify trends, deploy resources where they are most needed during an emergency, and more actively engage patients in their care.

Enhancements to our global healthcare system data infrastructure are necessary, and the need is immediate. These enhancements include the development and adoption of universal and standard data elements, as well as formatting, transmission and receipt technologies. The historical political and regulatory barriers should now be seen for what they were: unnecessary roadblocks that inhibited our readiness for the kind of crisis we have experienced with COVID-19. Building fluid pathways for health information will reduce redundant testing and enhance data analytics for use in treatment, population health and research. The future for data standardization is now, and the COVID-19 crisis may have provided the requisite catalyst for accelerated change.

Efforts to break down the barriers to data interconnectivity are sure to restart post-pandemic. In preparation, all players in the health system should review the interoperability of their systems and their API readiness, evaluate their participation in health information exchanges and even notification services, and identify how and by what methods they communicate with public health authorities to support disease identification and prevention. These information system building blocks will help the health system of the future position itself to identify trends proactively and ensure that the key participants in healthcare, especially patients and providers, have the tools and information to respond together to head off disaster, improve access and quality and lower costs. Privacy and security considerations will need to be addressed, but there must be a balance between those considerations and successful data movement for optimal healthcare. The tension is palpable, but strong leadership combined with the right technology ultimately rule the day.

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PROVIDERS

Even as the COVID-19 pandemic has exposed significant shortcomings of the US healthcare system, it has reaffirmed the foundational role that hospitals, health systems, physicians, nurses and other care providers play in that system. Hospitals and health systems have been, and continue to be, the front line in the clinical response to public health crises. Relationships with physicians, nurses and other care providers may change as well, insofar as front-line providers face high infection risks and deal with the personal impacts of the pandemic's broader economic repercussions.

> Hospitals need a playbook of pre-defined waivers of regulatory requirements and payment rules to help them respond to future pandemics.

Overall, provider organizations will need to continue innovating their business models. Cost containment, technological innovation and disease management likely will continue to encourage provision of healthcare services outside of acute care settings, even as provider organizations adjust their operations and human capital relationships to protect against further contagion and bolster provider alignment.

A Central Role in Public Health Crisis Response

Given their central importance, provider organizations (especially hospitals and health systems) should take a leadership role in working with government authorities to create new, more effective public health crisis playbooks. Ideally, these playbooks would include pre-defined waivers of state and federal regulatory requirements and payment rules to facilitate, pursuant to established plans (including those involving both public and private entities), the creation of "surge" inpatient and intensive care capacity, the deployment of the healthcare workforce to pandemic hotspots (on the ground or virtually), and the rapid deployment of new diagnostic and therapeutic technologies. In short, these pandemic playbooks would allow the extraordinary government and private actions that took place in response to COVID-19 to unfold pursuant to a more carefully established plan the next time a pandemic looms.

The Need to Adapt to Changes in Healthcare Delivery

Beyond the need for better public health crisis response strategies, provider organizations should be mindful of the other disruptions and opportunities highlighted by the COVID-19 pandemic—notably, new sanitization and social distancing requirements; potential shifts in both workforce and consumer

preferences; and the rapid, transformative shift to telehealth and associated opportunities for growth.

Prior to the COVID-19 pandemic, provider organizations were almost entirely brick-and-mortar businesses focused on episodic, in-person encounters, with the epicenter for care being the hospital campus. For generations, in-person visits and care were often the sole means of diagnosing and treating illness, as well as a requirement for obtaining reimbursement. In-person orientation is unlikely to change, given the physical nature of healthcare, but systemic reform efforts in recent years have focused on bending the cost curve by finding lower-cost situses for care and shifting away from fee-for-service reimbursement. The success of office-based physician practices, ASCs, urgent care centers and similar "off campus" venues also reflect increased consumer appetite for services rendered outside the hospital walls.

Although the COVID-19 pandemic underscores the importance of hospital services, the flood of COVID-19 patients in emergency rooms is likely to reduce consumer appetite for receiving lower acuity care in the hospital setting. The traditional hospital business plan will also be affected by the sudden expansion in reimbursable telehealth services brought on by the COVID-19 pandemic. Accordingly, hospitals should revisit their core business plans (including their capital and facility plans) and ensure that they reflect a thoughtful strategy based on anticipated shifts in consumer demand for off-campus care and more telehealth services. Physician groups should consider the associated tangential and consequential impacts as they develop their post-COVID-19 business plans. Provider operations, regardless of venue, are also likely to experience the human capital repercussions of the COVID-19 pandemic, requiring greater attention to both workforce wellbeing and provider alignment (economically, politically and culturally) within the organization.

Some human capital impacts have been immediate and obvious. For example, provider organizations have had to manage novel staffing disruptions as care givers fall ill themselves and deal with family illness. Similarly, state-wide restrictions on non-essential services resulted in sudden organizational and personal cash flow issues as service disruptions exposed the inherent downside risk of productivity-based compensation models and, simultaneously, the impracticality of fixed compensation expenses without supporting revenues. Even with the reopening of non-essential businesses, more thorough sanitization procedures and social-distancing requirements have prevented provider productivity from returning to pre-pandemic levels.

Provider organizations should also consider the lasting impacts that the pandemic experience may have on their human capital operations. Many traditional compensation models simply broke down during the COVID-19 pandemic, requiring organizations to triage with emergency measures that tried to balance platform cash flow stability with personal financial demands. Going forward, both employers and employees are likely to reevaluate those traditional compensation structures with heightened sensitivity for future "black swan" events. Moreover, even if social distancing and other containment restrictions ease as the pandemic subsides, some measures seem unlikely to be abandoned, with the potential for permanent reductions in efficiency for exam rooms, surgical suites, ambulances and similar hard assets. Finally, the long-term psychological and emotional tolls of pandemic response on front-line caregivers has yet to be fully understood. Just as the pandemic likely portends a shift in consumer demand, so too could

provider behavior feel a lasting impact from the COVID-19 pandemic experience. Each of these impacts will reverberate beyond hospital hallways and emergency response centers.

Functioning As True Systems

The COVID-19 pandemic has also highlighted the importance of healthcare systems that function as true systems. Healthcare systems have capability and flexibility to obtain and reallocate resources, whether consolidating service lines to create "surge" capacity; sourcing and acquiring personal protective equipment; or deploying physicians, nurses and other medical professionals where they are needed most. Moreover, the financial crisis that has accompanied this public health crisis has hit healthcare providers particularly hard. In combination, these factors will likely lead to increased interest in consolidation at all levels (*i.e.*, consolidation and/or acquisition of physician practices and transactions under which independent hospitals and/or small systems join with larger systems). For a meaningful number of healthcare providers, some type of strategic transaction is likely to be an existential or economic necessity. For others, the COVID-19 pandemic may mark yet another justification for a "strength in numbers" defensive strategy, as providers deal with the evolving healthcare landscape and reform efforts. Accordingly, provider organizations should begin to review their markets and consider transactional opportunities now. The opportunities might include traditional consolidation transactions or other structures that promote coordinated clinical action, such as horizontal collaborations between acute and post-acute providers, or may involve more innovative development efforts aimed at non-traditional service lines and shifts in healthcare consumption trends.

HEALTH INSURANCE AND COVERAGE

The COVID-19 pandemic may lead to long-term shifts in coverage and payment for healthcare, as well as increased integration of payors and providers.

Increased Use and Coverage of Telehealth and Digital Health Tools

The COVID-19 pandemic has expanded telehealth capabilities across the provider market and resulted in unprecedented consumer acceptance of telehealth services. These dynamics are likely to facilitate long-term opportunities for health insurers to enhance coverage permanently based on the adoption of telehealth services and digital health tools among insured populations.

Telehealth offers several potential benefits from an insurer perspective, often moving care to a more cost-effective setting and improving geographic access to specialist services. As the COVID-19 pandemic illustrates, telehealth also provides a unique method for continuing patient care while avoiding the risks of developing co-morbidities.

As patients become accustomed to receiving healthcare online, payors will continue to focus on how these services are reimbursed. Currently, almost all US states have laws governing private payor reimbursement of telehealth, with a handful requiring that in-person and virtual medical services be reimbursed equally. Government healthcare programs

have historically limited coverage for telehealth, and various laws—including those for privacy and state licensure—added to the complexity. However, the evolving regulatory landscape will continue to shape coverage policies and contractual relationships between payors and providers for digital healthcare technology. Payors are also increasingly seeking to add other digital tools, such as remote monitoring and healthcare apps, to the benefits that they can offer to their members. The experience of physical distancing is likely to accelerate innovation in coverage and adoption of such technology.

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Unprecedented Collaborations

The current crisis may also give rise to longer-term collaborations between payors and unexpected partners, such as drug manufacturers, diagnostic labs and digital health companies. The global focus on vaccine development and the unknown cost of an eventual vaccine may draw increased attention to a still-simmering debate surrounding drug pricing. Although health plan investment in provider organizations has been on the rise for years, the current economic challenges for providers may create new avenues for payors to invest in or acquire healthcare providers.

Expansion in Government-Funded Health Insurance Programs

With tens of millions of Americans losing both their jobs and their employer-based health insurance coverage, the number of individuals and families who are uninsured, and who may be eligible for Medicaid and Marketplace coverage, has increased significantly. Higher enrollment in these programs already appears to be driving some insurers back into the Marketplace in certain areas. If the economy remains affected by the pandemic or is slow to recover, increased payor interest in subsidized coverage may prove to be a broader trend over the next few years. The pandemic has also resulted in widespread attention on the US healthcare system—not all of it positive. This national attention may further mobilize political forces focused on expanding the government's role in providing health coverage, including Medicaid expansion and other mechanisms for potentially achieving universal health coverage. The current reliance on employer-based coverage is likely to be questioned, as higher unemployment may leave more individuals without healthcare—potentially compounding the issue in a time of public health crisis. Changes in who pays for healthcare will necessarily affect not only health insurers, but all other sectors of the health industry and consumer and provider behavior.

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Impact of Uncertainty on Rate Setting and Business Planning

The COVID-19 pandemic has created uncertainty around a broad range of issues, including potential resurgence of the virus, ICU utilization, development and cost of treatments, vaccine development and pricing, fluctuating moratoriums on elective procedures and consumers' ability to pay premiums. This uncertainty poses a challenge for health insurers working to evaluate and set rates for 2021 and future years. Rate-setting discussions occur at the state and federal level in roughly the middle of the year, meaning that a significant amount of information will be unknown at the time that prices for the next annual cycle are proposed and approved.

Churning Risk Pools

Widespread changes in employment status and income likely will result in significant churn (*i.e.*, the movement between different types of health insurance coverage and uninsured status) within the US health insurance industry. These changes in coverage negatively affect individual health via gaps in care, changing networks and interruptions in patient-provider relationships. Churn also makes it more difficult for health insurers to effectively manage the care of short-term plan members, and often results in increased costs due to uncoordinated and foregone care. With the downturn in the economy, this type of membership fluctuation may become the new normal for health insurers for the foreseeable future.

REGULATORY AND ENFORCEMENT

While the future of healthcare will likely involve continued relaxation of some regulatory requirements, the COVID-19 pandemic also gives rise to new regulations and relief programs that create new audit and enforcement requirements for the government. With shifting targets on the regulatory and enforcement landscape, providers should closely monitor developments that are relevant to their businesses.

Relaxed Regulations

Convincing regulators to extend or make permanent regulatory flexibilities and leniency implemented during the COVID-19 pandemic presents one of the greatest opportunities in a post-COVID-19 world. Relaxed regulations have affected several areas in the healthcare industry, most notably telemedicine and remote patient monitoring, and have prompted corresponding changes to cross-state licensure rules and supervision requirements. Similarly, hospitals, home health agencies and other providers have benefited from broad waivers of the Medicare hospital Conditions of Participation (CoPs). Those CoPs that are determined to have been unnecessary to ensure proper oversight and patient safety may not return after the crisis.

Transitioning to a New Normal

Conversely, not all of the flexibilities provided during the COVID-19 pandemic will remain, and the pandemic may yield new areas requiring additional enforcement scrutiny. A significant challenge will be tracking these regulatory transitions back to a new normal. Pandemic plans, the ability to distance patients, and the technology to evaluate patients remotely may all be mandatory in a post-pandemic world. Government investigations spanning timeframes during the crisis will require careful review against the flexibilities in place at the time.

Audits, surveys and enrollment actions that were temporarily suspended during the crisis will likely resume, but the potential strain on government resources in the post-COVID-19 unwinding phase may force government agencies to focus their attention on the most egregious violations.

> Relaxed regulations have affected remote patient monitoring, telemedicine, and changes to cross-state licensure rules.

Significant government resources are likely to be devoted to oversight, auditing and, almost certainly, enforcement actions related to healthcare providers' implementation and use of COVID-19-related waivers (such as the Stark Law and Hospital Conditions of Participation Waivers) and the CARES Act and similar COVID-19 relief funding. Indeed, certain federal government agencies and lawmakers have already signaled their intent to undertake robust reporting, auditing and enforcement activities.

Internal compliance activities should include planning for the unwinding of waivers, tracking billing compliance, documenting compliance with waivers (such as the Stark Law blanket waivers), and ensuring proper documentation and ongoing reporting compliance with Provider Relief Fund terms and conditions.

Long-Term Regulatory Outlook

As a result of the COVID-19 pandemic, some aspects of healthcare regulation will change permanently. We may also see new and improved processes to address flexibilities needed in the event of future pandemics, as well as continued changes to the way the US Department of Health and Human Services, CMS and the Office of Inspector General communicate guidance, including increased use of Interim Final Rules and FAQs.

HEALTH POLICY

The wide-sweeping economic impact of the COVID-19 pandemic has reset the backdrop for the 2020 election. Congress and the current administration will grapple with solutions for widespread unemployment, loss of healthcare coverage and provider struggles to reopen. Healthcare coverage and access were central issues in the health policy debate well before COVID-19, and they may be some of the most discussed topics in the months and years to come.

2020 Elections

The most significant factor shaping health policy in 2021 and beyond is the 2020 presidential election, as the candidates offer very different visions for the future of healthcare. Throughout the Democratic primary, former Vice President Joe Biden has remained committed to building on the Affordable Care Act (ACA). Unlike other candidates in the Democratic field early on who called for a single payor solution, Biden has supported a Medicare-like public option that would expand subsidies and tax credits for individuals purchasing insurance on the exchange, and would enable automatic enrollment into Medicaid for eligible individuals. In contrast, President Donald Trump has repeatedly pledged to do away with the ACA, although he has not articulated a plan to replace it. Around the edges, the Trump administration has offered alternative coverage types, such as short-term insurance and association health plans, and has taken action to chip away at the ACA and constrain Medicaid growth.

The dichotomy between the presidential candidates on the issues of health coverage and access is exemplified by a case currently before the Supreme Court of the United States. At issue in *California v. Texas* (previously known as *Texas v. Azar*) is the ACA's constitutionality following the elimination of the individual mandate penalty in 2017. *Texas*, supported by the Trump administration, argues that the individual mandate is unconstitutional because of the removal of the financial penalty and is not severable from the rest of the law, thus rendering the entire ACA unconstitutional. The Supreme Court will hear oral arguments in the next term, likely in October or November, with a decision expected in spring 2021.

> Depending on the outcome of the election and Supreme Court arguments, 2021 could prove to be tumultuous for healthcare.

Depending on the outcome of both the election and this case, 2021 could prove to be a tumultuous year for healthcare industry stakeholders grappling with insurance coverage and access issues.

State races in 2020 will also shape health policy, especially for the Medicaid program. During economic downturns, enrollment in Medicaid grows,

and we can expect the same to be true in the wake of the current crisis. States that have not yet expanded Medicaid will likely face pressure to do so as demand grows, even as state revenues decrease. As we start to see the lasting economic impact of the virus, more steps may be necessary to shore up the Medicaid program.

As we start to see the lasting economic impact of the virus, more steps may be necessary to shore up the Medicaid program.

Regulatory Priorities Post-Pandemic

This administration and the one before it have prioritized the move to performance based risk contracting models in Medicare and Medicaid. The pandemic underscored the vulnerability of the fee-for-service Medicare payment system and the administration took steps to shore up its alternative payment model portfolio and to retain momentum on model development and participation in 2021. The move to value-based care has been a rare point of agreement across the parties. Expect the focus on new models to continue regardless of the outcome of the election. While there may be differences in implementation and nuance of design, the transition away from fee-for-service will have renewed momentum coming out of the crisis.

Prior to COVID-19, the administration advanced sweeping regulatory changes intended to create greater transparency into prices charged by providers, pharmaceutical manufacturers and health plans, so that consumers of health services theoretically could more effectively price-shop. These administrative changes were all challenged in court, and the cases remain pending. The outcome of these cases will dictate how much progress the Trump administration can make through administrative action. Even if overturned, there is considerable bipartisan support for greater price and quality transparency, so expect this momentum to continue when law- and policymakers can return focus to matters other than COVID-19.

Congress Post-Pandemic

For most of 2019 and early 2020, the two priorities driving the congressional agenda were addressing surprise medical bills and reducing prescription drug prices. In early versions of stimulus legislation, House Democrats took aim at surprise billing by attaching prohibitions to relief funds. Both parties may attempt to revisit this issue following the 2020 presidential election, depending on where the nation is in its journey to recovery. In contrast, it is difficult to imagine Congress enacting any policy constraining payment to prescription drug manufacturers as they work to extract us from this pandemic. However, that outlook could change if a COVID-19 vaccine or treatment is offered at a price that catches the attention of federal lawmakers.

LIFE SCIENCES

As governments, health organizations and public health officials have scrambled to mobilize and coordinate a coherent, effective and data-driven response to the global pandemic, with varying degrees of success, the private sector—specifically the life sciences industry—has offered the world a beacon of hope.

Speed and Innovation in a Time of Crisis

The speed at which the biotech sector has pivoted toward innovation in the face of the global pandemic is unprecedented. Time will tell whether this more nimble approach is sustainable or has created its own set of risks that outweigh the benefits of delivering eventual results.

For example, Moderna, Inc., a clinical stage biotechnology company that typically works on pioneering messenger RNA (mRNA) therapeutics, has pivoted to develop what may be a promising COVID-19 vaccine with positive interim Phase 1 data, and recently announcing its plan for the final stage of clinical trials with 30,000 subjects set to be begin in July. The following timeline illustrates how quickly Moderna was able to pivot, innovate and begin developing this vaccine:

The speed at which the biotech sector has pivoted toward innovation in the face of the global pandemic is unprecedented.

- December 16, 2019: The first documented case of COVID-19 was admitted to a hospital in Wuhan, China, with a severe pneumonia-like illness.
- December 31, 2019: Researchers in China identified a new virus that had infected dozens of people, also with pneumonia-like illnesses.
- January 11, 2020: Chinese state media reported the first known death from an illness caused by the virus, and researchers shared the genetic sequence of COVID-19.
- January 13, 2020: Fewer than two days after the first known death caused by COVID-19 in Wuhan, China, and almost two months before the World Health Organization made the assessment that COVID-19 can be characterized as a pandemic, Moderna finalized the sequence for mRNA-1273 for a COVID-19 vaccine and mobilized toward clinical manufacturing.

Over the subsequent months, despite global economic uncertainty, the health, technology and life sciences sectors have converged with the investment community to innovate, collaborate and respond to unmet needs caused by the pandemic. The global race

to develop successful tests, treatments and vaccines for COVID-19 has unleashed a dizzying amount of activity from biotech companies. According to Informa Pharma Intelligence, by the end of May 2020, there were 140 experimental treatments and vaccines for COVID-19 in development, including 11 in clinical trials.

Economic Strength of the Life Sciences Industry

The life sciences sector has demonstrated resilience during the economic turbulence caused by the global pandemic. Biotech companies are awash with more cash than at any time in the sector's history, with venture capital funding reaching a peak of $5.5 billion in the first three months of 2020, record numbers of strategic collaborations and partnerships, continued strong IPO activity1 and the NASDAQ Biotechnology Index nearing a five-year high. Since the beginning of March 2020, life sciences venture capital funds have raised more than $5 billion in new investment funds. Moreover, as with the 2008/2009 recession, it appears that the biotech sector is less sensitive to macroeconomic swings, which provides some confidence that there may be less disruption to the drugs and therapies currently under clinical development. While the danger from COVID-19 persists, the need for solutions and the willingness to make investments in search of those solutions will continue.

Government Investment in the Life Sciences Sector

The COVID-19 pandemic has demonstrated that the US government, specifically the Biomedical Advanced Research and Development Authority (BARDA), is willing to invest in the biotech sector. BARDA has awarded more than $2 billion to support COVID-19 vaccine development efforts, including $483 million to Moderna to accelerate the development of its vaccine, $456 million to Johnson & Johnson to accelerate vaccine research and ramp up production, $30 million to Sanofi to collaborate on a flu vaccine for COVID-19 and $38 million to Merck for COVID-19 vaccine development in connection with its Ebola virus vaccine. Given the severity of the economic downturn and the belief that government support is critical to recovery, it is likely that government support will continue and become more anticipatory relative to future viral and biological risks.

> Since the beginning of March 2020, life sciences venture capital funds have raised more than $4 billion in new funds.

COVID-19 is Reshaping the Pharmaceutical Supply Chain

According to the Chemical Abstracts Service (CAS), the COVID-19 pandemic did not seriously impede the production and shipment of pharmaceuticals in the first quarter of 2020, particularly since China's

[1] According to Renaissance Capital - Biotechs make up almost two-thirds of IPO activity through the end of June 2020

manufacturers were up and running again by early February. However, the supply chain may be tested in the coming months, as inventories of backup materials will be used and deliveries delayed. Further, as the world has recognized the dominance China plays in the global supply of active pharmaceutical ingredients and their chemical raw material, the United States has led an effort to rebalance the supply chain. For example, BARDA awarded $354 million to Virginia-based Phlow Corporation for advanced manufacturing of essential medicines at risk of shortage, including medicines for the COVID-19 pandemic response, and up to $285 million to Paratek Pharmaceuticals for the onshoring of the manufacturing supply chain in the US.

Exponential growth in the use of artificial intelligence to further speed drug discovery and development can be expected.

Machine Learning and Artificial Intelligence

Artificial Intelligence (AI) is also being deployed to screen billions of molecules for COVID-19 treatments, the MIT-IBM Watson AI Lab is funding 10 research projects aimed at addressing the health and economic consequences of the pandemic, and various efforts to model the COVID-19 outbreak and provide scientific insights are being leveraged using AI and machine learning tools. In addition, there has been robust private sector investment in companies using AI for drug development. According to PitchBook, there are 210 AI-powered drug discovery companies, with $8.14 billion in capital investments. Exponential growth in the use of AI to further speed drug discovery and development can be expected.

COVID-19 Regulatory Pathways

Almost every major pharmaceutical company worldwide is racing to develop effective therapeutics and vaccines to combat COVID-19. Although some of this effort—particularly in the case of potential vaccines—is aimed at creating, testing and rolling out new treatments and preventatives, a significant part of this push involves taking a second look at existing compounds and possibly repurposing them to treat or reduce the rate of COVID-19 infection. To support this effort and enable faster access to promising treatments, regulators in the United States and the European Union have established several options that loosen or revise certain restrictions and simplify investigative and regulatory approval pathways.

US Food and Drug Administration (FDA)

In response to the COVID-19 crisis, the US Food and Drug Administration (FDA) has used several pathways and initiatives to facilitate or expedite access to COVID-19 therapeutics and vaccines. For example, the FDA has issued emergency use authorizations (EUAs) that permit the use of unapproved medical products, or the off-label use of approved medical products, to prevent, diagnose or treat COVID-19 when—among other criteria—no adequate, approved and available alternative exists. The FDA is expediting the provision of feedback on development plans for COVID-19 vaccines and

therapeutics through the pre-Investigational New Drug (IND) application process, which intends to help manufacturers address key regulatory questions before beginning clinical (human) trials. The FDA has also implemented a Coronavirus Treatment Acceleration Program (CTAP), a special emergency program under which the agency will triage requests from developers of new drugs and biological therapies (excluding vaccines), connect them with appropriate FDA staff and provide rapid, interactive input on product development plans and/or study protocols. Additionally, the FDA has used its expanded access (or compassionate use) program to give patients access to certain treatments outside the scope of clinical trials. The FDA is expected to continue using these tools for the duration of the public health emergency. However, the agency's willingness to consider aggressive action to expedite the delivery of novel therapeutics and vaccines beyond the pandemic will likely depend on several factors, including (but not limited to) the agency's assessment of the risk/benefit balance of its decisions during the pandemic, and legislative activity that could modify FDA's "usual" regulatory processes.

Finally, the US government has launched Operation Warp Speed, which can allow the federal government to select promising COVID-19 vaccine candidates, offer funding and resources, fast-track trial and aid in manufacturing efforts. Though the details of the program are expected to be shared in the coming weeks, the goal of the program is to have 300 million vaccine doses ready by January 2021. While this project does not create any new regulatory pathway for vaccines, it does highlight a more intensified push by the federal government to infuse greater financial resources into the vaccine development process.

EU European Medicines Agency (EMA)

Like the FDA, the EU European Medicines Agency (EMA) and Member States' national drug authorities are focusing attention on—and expanding access to—off-label use alternatives and compassionate use programs, prioritizing the delivery of scientific and procedural advice to COVID-19-related projects, accelerating authorization procedures and granting provisional and conditional drug marketing authorizations for drugs intended for use in a public health crisis—of which COVID-19 is a textbook example. Given the extent of the pandemic, its carnage on both human and economic levels, one can anticipate significantly greater government support and involvement to head off future epidemics. Efforts are likely to include an intensified and proactive review of not only health and life sciences supply chain issues, but matters surrounding food, water, fuel and other health and economic building blocks.

The FDA has used its expanded access to give patients access to treatments outside of trials.

TRANSACTIONS

Although transaction volume in the healthcare industry has reached all-time highs in recent years, the sudden and unanticipated cash flow and operational disruptions resulting from the COVID-19 pandemic have slowed most M&A and other transactional efforts for both strategic and financial investors. Parties have struggled to agree on valuation adjustments for the pandemic impact, and sellers have been reticent to bring new platforms to market.

However, robust investor appetite persists, particularly among private equity funds sitting on considerable dry powder for new investment even prior to the pandemic. Credit markets also remain favorable for leveraged buy-outs, with current monetary policy promising low interest rates for debt financing in the near term.

The lasting impact of the COVID-19 pandemic on healthcare transactions is multi-faceted, with an eventual surge in deal volumes seemingly inevitable as parties cope with the financial and operational impacts on current businesses and execute on strategies for the "new normal" once the current uncertainty subsides. A few observations:

- Uncertainty as to the duration of public health restrictions to address the COVID-19 pandemic continues to inhibit deal-making, with perceptions of a "light at the end of the tunnel" likely unlocking a surge in deal activity. Already investors are exploring ways to beat the curve by underwriting some uncertainty in their valuation assumptions and correspondingly exploring options to hedge that risk through deferred payments and contingencies, which have to navigate a complicated lattice of economic, regulatory, tax and general alignment issues.
- With respect to EBITDA impacts, we anticipate that parties will generally look past short-term, non-recurring negative impacts to EBITDA arising from COVID-19 pandemic restrictions. However, smart investors will not simply assume a "return to normal," but will rather endeavor to evaluate what "new normal" will emerge for the target business. This is particularly pertinent for private equity investors looking for new platforms. By contrast, strategic buyers may consider their own COVID-19 experience to afford sufficient insight on a complementary target business's future revenue and expense profile, utilizing pre-COVID-19 pandemic EBITDA numbers, or extrapolations therefrom, for valuation purposes, particularly where the purchase consideration includes a sizable equity component.
- The impact of COVID-19 on transaction multiples is less clear, with insight depending on when and to what extent the transactional market ramps back up and how the pandemic experience impacts credit terms. For private equity, the pandemic has stressed platforms built on highly-leveraged, buy and build strategies. Investors that failed to adequately plan for reduced productivity among selling providers have not found their current lenders to be particularly sympathetic in managing through current liquidity needs as a result of stay-at-home orders and elective surgery prohibitions across most states. Even before the COVID-19 pandemic, some lenders had begun to lose appetite for highly-leveraged, single-specialty physician practice management and dental service organization businesses. Similarly, many equity investors were shying away from sky high valuations that require high leverage and high-consequence financial

modelling assumptions. Accordingly, negative lender and sponsor experiences with COVID-19 disruptions to existing investments may ultimately cool (or even depress) multiple expansion from the pre-pandemic highs. At the same time, the systemic drivers toward consolidation, coupled with the continued need for existing "dry powder" (both debt and equity) to be invested, could very well preserve those pre-pandemic multiples.

- Valuation and credit distress during the COVID-19 pandemic is also likely to further depress larger cap buyer appetite to compete for businesses at outsized multiples that have exhibited rapid growth through bolt-on acquisitions without a proven track record of operating in an integrated manner at scale. This trend was developing before the pandemic, and has exacerbated the situation for many, as poorly integrated platforms fracture without the economic, political and cultural integration needed to promote stability and performance through turbulent times.
- The adverse impacts of the COVID-19 pandemic notwithstanding, there will continue to be a premium market for quality assets that demonstrate the economic, political and cultural cohesion to weather the storm. With significant investor appetite remaining, premium multiples are likely to remain if there is a scarcity of scaled healthcare platform businesses that have demonstrated the ability to not only acquire smaller businesses, but integrate them and position them well for sustainable, organic revenue growth. Relatedly, we expect a renewed emphasis by investors on earnings growth through organic avenues beyond "stacking" acquired EBITDA, including adoption of more efficient staffing models to leverage the accelerated adoption of telemedicine, expanded use of technology and data to improve the patient experience and reduce cost, and concerted efforts to develop alternative care delivery and payment models in a far more comprehensive manner than existed before the pandemic.
- The COVID-19 pandemic has evidenced a need for greater connectivity among patients, providers, payors and other stakeholders. Overall success will depend on how well healthcare players collaborate to build the system around the consumer. Accordingly, we can expect to see more data and information collaborations, using the right technology with the right sensitivity to patient needs, to bring forth a new mode of data use. Systemic improvements need to ensure that current data is available on demand for multiple uses, including treatment, payment, healthcare operations, trend identification, research and population health. Given the exposed vulnerabilities in the current system, the drive to reimagine and implement an even more sophisticated data infrastructure will only continue to accelerate.
- If there was ever a need for greater collaboration in healthcare, it would be now. The pandemic has exposed gaps in the process of healthcare delivery and opened new opportunities that can be addressed when participants across health, life sciences technology and other subsectors join forces. Many investors are already exploring business combinations, joint ventures and other innovative transactions to capitalize on these opportunities and to address the new set of challenges facing both providers and patients to deliver and receive care safely and effectively.

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CONCLUSION

As the health industry continues to tackle the immediate challenges of the COVID-19 pandemic, stakeholders across the board should prepare for a "new normal" akin to the lasting changes seen in the travel industry following the events of September 11, 2001. The exact parameters of this new normal are still in flux, but this period of transition presents numerous risks for those unprepared or unwilling to adapt and real opportunity for those that are. Which direction will your organization take? To understand how McDermott can help you see further around the corner "after the curve," please contact your McDermott lawyer.

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