COVID-19 Pandemic Could Accelerate Recent U.S. Healthcare Growth Trends

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One hundred years after the 1918 Spanish Flu, the world is facing another pandemic: COVID-19. Government and healthcare officials are working around the clock to flatten the curve and slow the spread of coronavirus.

In the United States, the number of infected patients continues to rise as regulators enable more test availability and capacity to frontline healthcare workers. To help accelerate the availability of tests, the Food & Drug Administration (FDA) announced a new policy last Monday that makes diagnostic tests developed by commercial manufacturers more widely available in laboratories. This solves a critical need as the number of positive coronavirus cases in the U.S. grows daily, putting additional pressures on the healthcare system.

In response to the outbreak, researchers developing COVID-19 vaccines are progressing through clinical trials on an accelerated basis as numerous regulatory changes aim to streamline life sciences protocols. President Donald Trump also invoked the Defense Production Act, which, if the full authority of the law were to be used, would allow the government to direct companies to manufacture necessary equipment and offer financial incentives and assistance to expand private industry production. Additionally, Centers for Medicare & Medicaid Services (CMS) took action—last week CMS lifted Medicare telehealth regulations permitting doctors to practice across state lines, if they have an equivalent active license from another state, expanding patient access to telehealth services.

Impediments, of course, still exist. While testing capacity has expanded, hurdles remain in the test kit and component supply availability, as well as kit distribution, and biospecimen collection and logistics. Though telehealth services and other remote patient engagement and access solutions may now have a broader mandate and operational flexibility, their success hinges on their ability to scale in a way that ensures seamless care coordination. The safety and health security of all healthcare professionals is paramount to meeting the rapidly escalating demands for care the world is encountering.

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As the world battles the pandemic, M&A activity in many sectors has ground to a halt. Yet private equity groups (PE) have an opportunity to consider select healthcare segments with accelerated growth drivers, deploying their dry powder into industries which may see unprecedented demand during the crisis—and potentially permanently shift the way Americans receive medical care in a post-COVID-19 world. Consolidators interested in healthcare should take note of the following six drivers and themes:

1) Critical Diagnostic Tests or Components, and Pharmaceutical Ingredients

COVID-19 Impact: More COVID-19 tests will be made available to patients displaying symptoms through the FDA's new policy. However, as more tests are administered, there will be a race to stay ahead of the supplies needed to make the tests—reagents, RNA extraction kits and swabs—to avoid a shortage. Some manufacturers are reworking tests in anticipation of the shortage, but this is not sustainable long term. Companies, like European manufacturer Qiagen, are ramping up production, but they face unprecedented demand. Companies like Roche and Hologic, that received approval to manufacture and ship tests through the FDA Emergency Use Authorization (EUA), are also optimizing their plants to rapidly manufacture tests.

Drivers & Opportunity: Middle market PE have long been interested in diagnostic test manufacturers as well as diagnostic component and pharmaceutical ingredient suppliers, but now there is a heightened awareness of those companies. The demand for research and development capabilities, validated manufacturing infrastructure and sourcing knowledge (supply chain diversity/security) is only increasing with the COVID-19 pandemic and is likely to remain robust long after it has passed. The customer base for components and ingredients is typically sticky, as those elements are often "scoped in" with product approvals or researcher preferences, and are steps removed from end-market reimbursement exposure, leading to long-term business sustainability. Despite decades of consolidation, numerous privately-held businesses remain with attractive growth potential and cash flow characteristics.

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2) Unique Lab Testing Infrastructure

COVID-19 Impact: The United States is capable of processing thousands of samples at a time. Because of the FDA's recent rulings, key industry players Laboratory Corporation of America Holdings and Quest Diagnostics Inc. can greatly increase the number of tests processed per day. The American Clinical Laboratory Association (ACLA) expects to exceed 280,000 tests per week by April 1 nationwide. With patient financial responsibility for the tests being waived, the ACLA has asked Congress to support an emergency laboratory surge capacity fund of $5 billion to ensure labs have the necessary resources needed to fulfill that promise.

Drivers & Opportunity: PE investment in lab services has slowed in recent years due to reimbursement pressures from Protecting Access to Medicare Act (PAMA) and select testing segment-specific issues, both regulatory and reimbursement-related. COVID-19 testing demand could pique private equity interest as clinical lab testing provides a significant amount of data. In a world rapidly moving toward precision medicine, data is critical not just for therapeutic decisions, but also for drug discovery and development, clinical trial patient recruitment, population health management, patient awareness and disease monitoring. The COVID-19 pandemic has thrust the relevance and medical necessity for clinical lab data—whether screening, diagnostic or monitoring—back into the spotlight.

3) Telehealth & Remote Care

COVID-19 Impact: As people around the country—particularly seniors, given their acute vulnerability to the virus—are encouraged to shelter in place, remote care can connect patients with providers digitally in their homes, reducing risk of exposure. The new CMS rules apply to all covered telehealth services in Medicare, not just related to COVID-19, and will help keep Medicare beneficiaries out of doctors' offices and hospitals as care is delivered directly to homes. The recent changes allow Medicare telehealth services to be performed anywhere in the country, where previously the physician had to be licensed in the state where the patient receiving care lived. CMS has waived this requirement for Medicare patients and many governors have requested a waiver for Medicaid patients as well.

Drivers & Opportunity: Prior to the COVID-19 outbreak, remote care and telehealth services were an attractive investment theme for many healthcare PE groups because of their ability to relieve pressure on hospitals and physician offices as well as accurately manage care in real time. The CMS rules are temporary and expected to revert to previous rules post-crisis; however, the experience of payors, patients and providers in this time may prove to be a catalyst to bring about permanent changes.

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4) Patient Centricity & Specimen Logistics

COVID-19 Impact: As the practices of social distancing and remote care are leveraged to connect patients with providers, nurses and biospecimen collection personnel are being physically deployed to the home and workplace to bring screening services and care to patients. Employers are also able to test essential employees before their shifts, which proved an effective preventative strategy in China. What's more, deploying patient-focused, in-home clinical trial solutions can help support pharmaceutical and biotechnology companies with ongoing clinical trials continue to access trial participants, maintain continuity and reduce costs.

Drivers & Opportunity: Patient centricity and specimen logistics have seen a renaissance of PE interest given the benefits and complexities of remote visits. PE and strategic buyers alike have been on the hunt for scarce assets related to in-home or virtual clinical trials, hubs, health economics and outcomes research (HEOR), post-market surveillance, or biospecimen collection and logistics. The COVID-19 pandemic may be the start of removing regulatory barriers permanently and creating accelerated demand for managing patients and participants in a patient-centric manner. Providing care or testing services in a home-based or remote setting—whether for a clinical trial or routine health management—is efficient, cost-effective and beneficial to the healthcare ecosystem.

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5) Patient Engagement and Healthcare Consumerism

COVID-19 Impact: Given the criticism related to the slow rollout of tests in the U.S., direct-to-consumer home testing companies have entered the conversation. Everlywell and Nurx, home testing companies, announced the addition of COVID-19 tests to their test offerings. While these companies have indicated that Clinical Laboratory Improvement Amendments (CLIA) certified labs will process the tests, how the FDA will regulate and approve the tests is to be determined. Most recently the FDA updated its EUA guidelines to specifically bar the use of at-home sample collection for COVID-19 tests. Ensuring the tests are approved by the FDA is a risk associated with home testing, as less reputable companies and scammers alike have marketed tests not yet approved by the FDA. With FDA approval, home testing has the potential to become a popular route as Americans become more engaged in their healthcare, individuals seek to minimize patient exposure in overcrowd ERs, and companies look to reduce a strain on the hospitals and physician offices.

Drivers & Opportunity: The COVID-19 pandemic may be the first time a general consumer knows the difference between a screening, diagnostic and monitoring test. Consumers are washing their hands, ordering and paying for in-home test kits, and strictly adhering to their medication and probiotic regiments. Healthcare brands are becoming part of the lexicon as Americans closely follow the COVID-19 updates and become more engaged in their care. As a result, companies that put the patients first and make access to their products or services easier could grow and become more attractive to investors long after COVID-19 moves to the rearview mirror.

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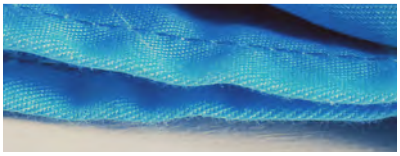
6) Patient-Directed Home Care Providers

COVID-19 Impact: Home health and personal care services agencies have traditionally employed a model whereby a single caregiver visits multiple patient residences per shift. Given the highly contagious nature of COVID-19 and its disproportionate impact on the senior population, the home healthcare industry has implemented extreme precautions to avoid putting patients and caregivers at risk and fueling further spread of the virus.

Drivers & Opportunity: Patient-directed care agencies, by comparison, use a model whereby a single caregiver, typically an immediate family member designated by the patient, is properly trained and supervised for assisting the patient with activities of daily living —bathing, dressing, toileting or feeding—to preserve that person's independence and ability to age at home. State governments are acting to rapidly accommodate new enrollments in self-directed programs to ensure that eligible populations can be served in their homes and avoid moving people into institutional settings where the virus can thrive. The federal government recently announced an increase in the federal medical assistance percentages (FMAP) to help states offset increased costs related to the expansion of programs such as patient-directed home care.



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COVID-19 is rapidly changing how clinicians and other members of the healthcare ecosystem provide patient care, and in the process, the entire healthcare landscape. Regulatory changes implemented during the pandemic may lead to permanent changes in how people receive and interact with their healthcare. At a minimum, these changes will inform discussions about regulations that need to be updated via a more engaged and knowledgeable voting public. In the process, new opportunities in healthcare could arise, encouraging deals in segments in the coming months.

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