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Opportunities and challenges in an evolving market

2021 healthcare and life sciences investment outlook

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Table of contents

Introduction: The pandemic year in review

The healthcare and life sciences industry and subsectors have weathered the most difficult economic year in modern history. However, despite the massive financial and social disruption caused by the global pandemic, many companies in the industry fared better in 2020 than other sectors of the economy, and companies in several subsectors maintained unprecedented momentum in the deal market.

Q1 2020

As we began 2020, the headlines at the annual JP Morgan Investment Conference were bullish on both the state of the healthcare and life sciences industry and the direction of investment for the coming year. Early in the first quarter, before the world became aware of the reach and magnitude of the COVID-19 virus, investment activity was robust and increasing.

Late in the quarter, however, economic activity was curtailed to stop the spread of COVID-19, immediately affecting a wide range of industries, including companies in many healthcare and life sciences subsectors. Almost overnight, the pandemic became the most all-consuming headwind in recent healthcare and life sciences history.

Q2 2020

Around the world, citizens, business leaders, and investors adjusted to the shocking news that COVID-19 was not a growing regional health threat, but a global pandemic. This was a situation for which both healthcare systems and governments were largely unprepared. Many urban hospitals in the U.S. were quickly overwhelmed by the volume of patients and couldn't access necessary personal protective equipment (PPE) or ventilators. Elective surgeries were cancelled, and leaders of hospitals, physician practices, and manufacturers of medical devices used in elective surgeries wondered if they would survive financially. The predominantly uncoordinated and inconsistent responses of governments – in the U.S. and around the world – had a ripple effect across healthcare and life sciences. As the world went into varying stages of social and travel restrictions, healthcare market activity pivoted to meet new demands brought on by the pandemic, while life sciences investment activity continued to accelerate, driven by optimism about COVID-19 vaccines and treatments, as well as continued interest in breakthrough therapies.

Between the beginning of the year and the spring, the U.S. government instituted numerous actions to provide relief and flexibilities to the healthcare industry as it began responding to the COVID-19 pandemic.[1] On January 31, the Secretary of Health and Human Services (HHS) declared a public health emergency (PHE), retroactive to January 27, paving the way for additional support for state, tribal, and local health departments. President Trump signed into law the Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 on March 6, providing $8.3 billion in supplemental funding to support pandemic responses by the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and other agencies. On March 13, President Trump made the determination that the severity and magnitude of the pandemic warranted an emergency declaration and determination under both the National Emergencies Act and the Stafford Disaster Relief and Emergency Assistance Act. Using the authority granted through these emergency declarations, the Centers for Medicare and Medicaid Services (CMS) issued a number of blanket waivers to support providers for the duration of the PHE.

[1] S.L. Kocot, T. McCutcheon, and R. White, COVID-19 National Emergency Declarations and Associated Executive Orders, KPMG, March 20, 2020.

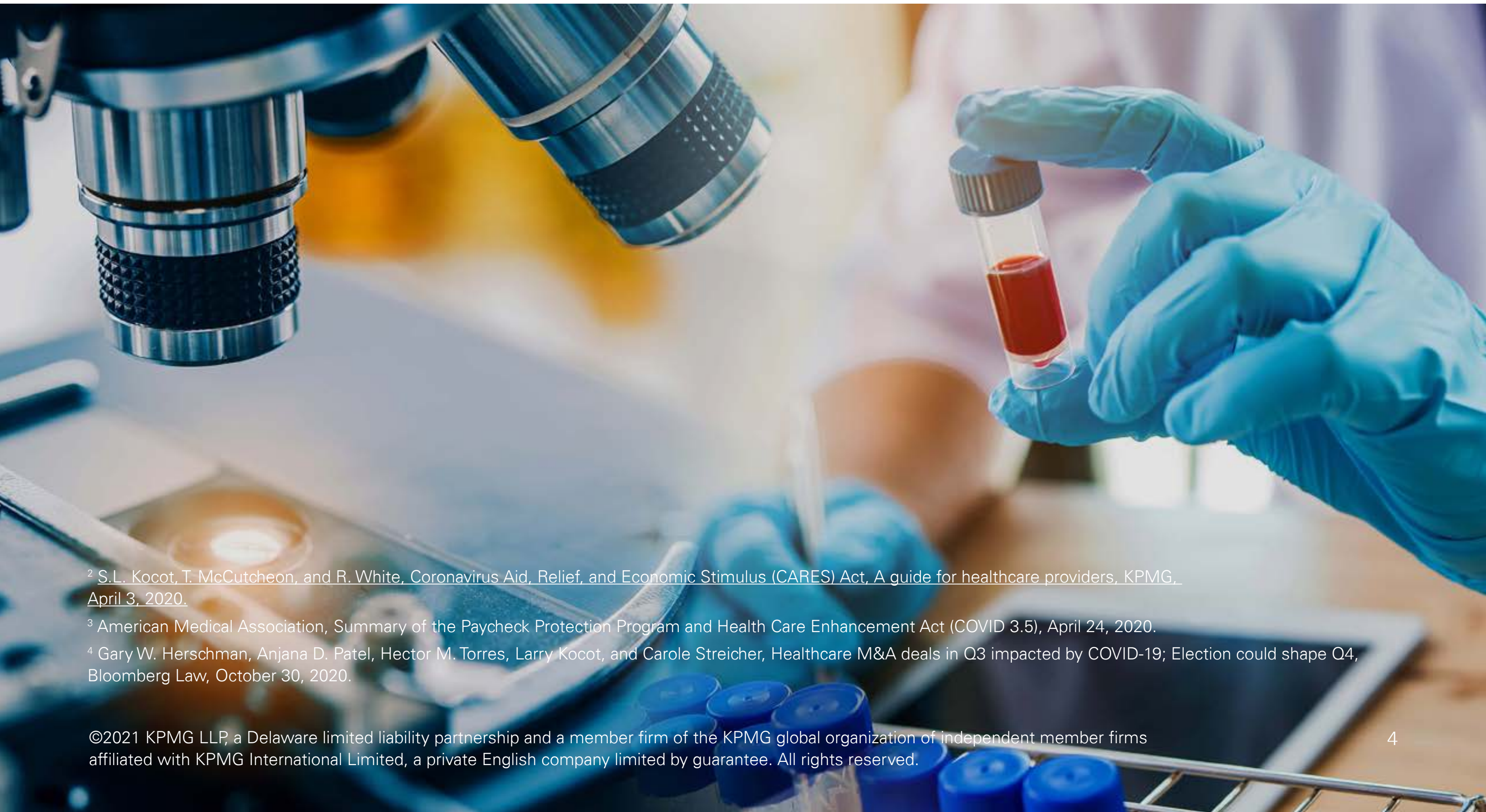
On March 27, Congress and President Trump enacted the Coronavirus Aid, Relief, and Economic Security (CARES) Act, a $2.2 trillion relief and economic stimulus bill, of which $180 billion was earmarked for health-related spending,[2] and the Paycheck Protection Program and Health Care Enhancement Act, which included funding for healthcare providers and testing.[3] Assistance was offered to hospitals and physicians through the Provider Relief Fund, insurers were required to cover COVID-19 testing and vaccinations without patient cost-sharing, and funding was provided for Operation Warp Speed, which was designed to expedite the development and launch of COVID-19 therapeutics and vaccines, many of which received emergency-use authorization in record time, while others remain in the early stages of development.

Q3 2020

Over the summer, hospitals and physicians began to recover, while labs and diagnostics manufacturers shifted service and product offerings to meet COVID-19-related demands. Providers quickly embraced telehealth waivers, vastly increasing the use of remote visits to treat home-bound patients. Other segments of the healthcare and life sciences industry responded to government actions and programs. At the same time, some physician practices began to realize that, as visit volumes remained volatile, capitation models could offer more cash-flow consistency. On the investment front, pressure to deploy capital, a strong deal pipeline across several healthcare and life sciences subsectors, and optimism about emerging opportunities in biopharmaceuticals continued to fuel market activity.[4]

Q4 2020

As the pandemic wore on into the fourth quarter, the American public showed noticeable COVID-19 fatigue. The handling of the pandemic became a defining issue for many Americans as they prepared to go to the polls in November. After one of the most incendiary and politically charged U.S. presidential elections in our nation's history (see sidebar), the debate among policymakers finally returned to the need for additional stimulus and government actions, but not before infections, hospitalizations, and deaths across the country reached record levels. As the year ended, hospitals were overwhelmed by COVID-19 on a broader nationwide scale than in the spring of 2020.



[2] S.L. Kocot, T. McCutcheon, and R. White, Coronavirus Aid, Relief, and Economic Stimulus (CARES) Act, A guide for healthcare providers, KPMG, April 3, 2020.

[3] American Medical Association, Summary of the Paycheck Protection Program and Health Care Enhancement Act (COVID 3.5), April 24, 2020.

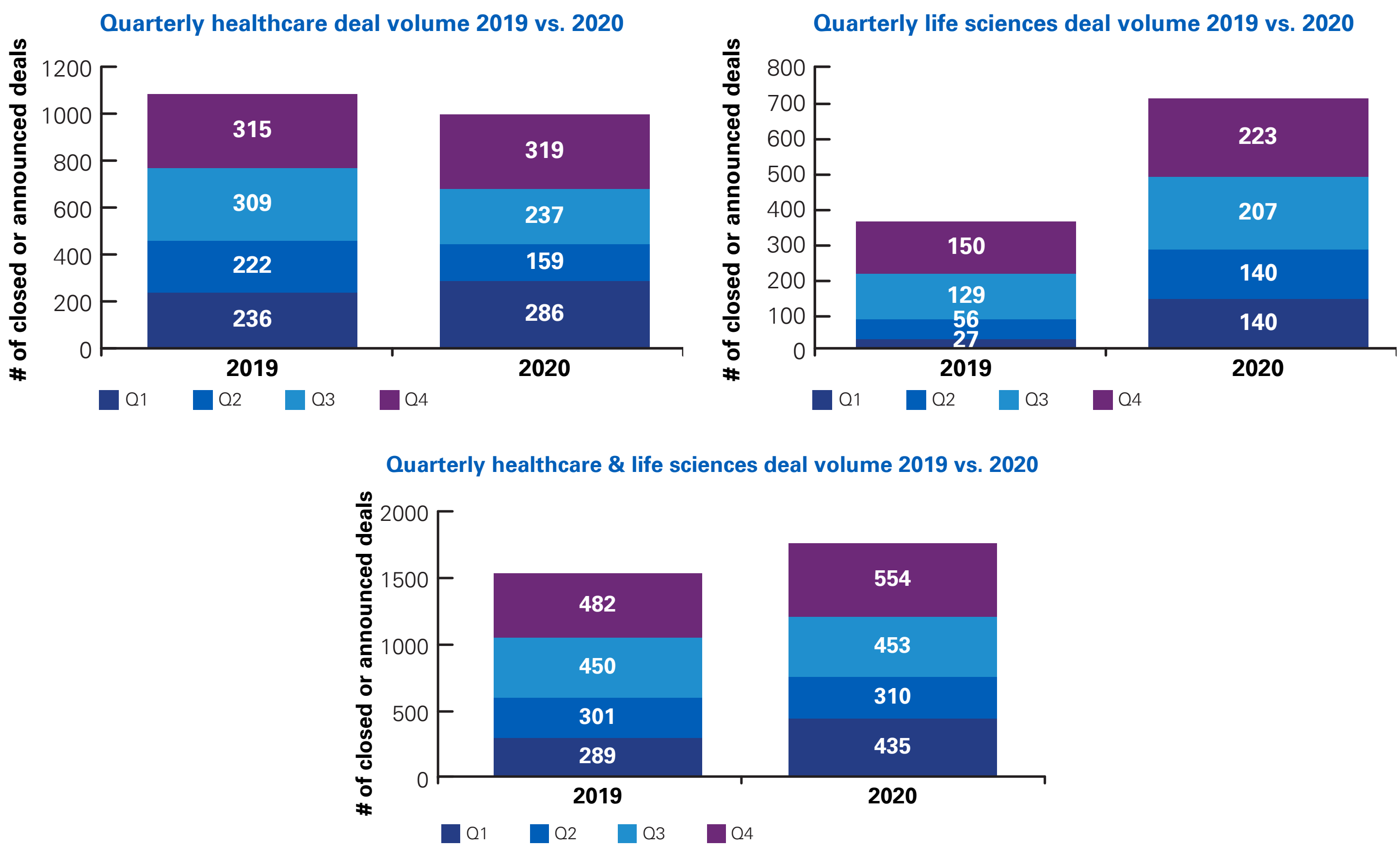
[4] Gary W. Herschman, Anjana D. Patel, Hector M. Torres, Larry Kocot, and Carole Streicher, Healthcare M&A deals in Q3 impacted by COVID-19; Election could shape Q4, Bloomberg Law, October 30, 2020.

Investing perspective

It is notable that, at a time of unprecedented disruption, the deal market was still active in 2020, albeit with a trend toward smaller, more creative deals. While the dollar value of deals is not publicly available across healthcare and life sciences and may be lower overall than in 2019, the volume of healthcare and life sciences transactions was 15 percent higher in 2020 than in 2019 (Exhibit 1). Healthcare deals slowed during the second quarter and came back by the end of the year. At the same time, there was steady interest and activity in life sciences transactions despite high valuations.

Does this growth in the volume of deals (many of them smaller in value) and higher valuations signal a trend in biopharma and related subsectors? Did investors deploy capital to take advantage of opportunity presented by the worldwide health crisis, or were they acting in anticipation of a brighter horizon ahead? Finally, given the market environment in 2020, how should investors across healthcare and life sciences approach 2021? This report and our discussions with clients aim to answer those questions.

Exhibit 1. Healthcare & life sciences deal volume, 2019 vs. 2020



Note: Data does not include cannabis or long term care REIT deals. Total HCLS deals include an "other" category which is not included in either the HC or LS breakout graphs

Source: Adapted from Gary W. Herschman, Anjana D. Patel, Hector M. Torres, Larry Kocot, and Carole Streicher, Forthcoming, *Bloomberg Law*, January 2021.

The 2020 elections: Implications for investors

After one of the most contentious presidential elections in our nation's history, Joseph Biden and Kamala Harris were sworn in as President and Vice President of the United States of America, respectively, on January 20th. Additionally, Democrats now control both chambers of the 117th Congress for the first time since the 111th Congress (2009-2011), with a slim majority in the House of Representatives (222-211) and the slimmest possible majority in the Senate (a 50-50 split with Vice President Harris as the tie breaker).

While control of the Senate will create a much easier path to confirmation for Biden administration appointees, passing legislation to further the Biden agenda will be a more complex undertaking: most legislation will require 60 votes in the Senate to overcome Republican objections (filibuster). A limited legislative agenda may qualify and be passed under budget reconciliation rules (i.e., measures impacting spending, revenue, and the federal debt limit), which require only a simple majority vote in the Senate. While the Biden administration will have to work closely with House and Senate leadership to maintain party discipline and secure the votes of Democrats in both houses of Congress for even limited legislative success, they will need bipartisan support to ensure a comfortable margin that will allow for overall legislative progress.

The Biden administration has set forth four immediate priorities: (1) the COVID-19 pandemic, (2) economic recovery, (3) racial equity, and, (4) climate change. Senator Chuck Schumer has also stated that his immediate priority as Majority Leader will be more stimulus relief.

Given these priorities and political dynamics in Congress, the Biden administration and Congressional leaders must carefully consider what priorities may attract bipartisan support and whether there is enough consensus to pass bills under regular order. Legislation on pandemic relief and immediate health imperatives will provide an early signal about bipartisan cooperation; reconciliation will likely be considered for qualifying priorities that may not be able to generate enough bipartisan support through regular order in the Senate.

We expect a long list of healthcare and life sciences policy priorities to be considered in the context of the Congressional agenda, including bolstering the Affordable Care Act (ACA) through increased premium support and providing additional incentives for states to expand Medicaid, but whether they can attract bipartisan support remains to be seen.

Proponents of larger scale, potentially more contentious legislative proposals (e.g., public option or lowering the Medicare eligibility age to 60) may be challenged to attract the support needed, even if sought through a reconciliation package; as a result, sweeping health reforms are less likely in this Congress.

Proposed legislation that translates into savings, such as measures to reduce prescription drug prices and certain tax code changes, would be budgetary offsets in a reconciliation bill. Indeed, it is possible that there could be more than one reconciliation bill in calendar year 2021: one in FY 2021 and another in FY 2022. Offsets will be critical given the need for more economic recovery spending along with increasing concerns about a rapidly growing national debt and other countervailing fiscal and budgetary constraints.

It should be noted that major changes to the tax code could present significant headwinds for investors, depending upon what is ultimately enacted into law. Development of a reconciliation package is likely to occur throughout the spring but attempts to pass any major tax-code changes within reconciliation are unlikely until the pandemic is under control and there is greater stability in the economy.

Given the complexities of the legislative agenda, we anticipate that proposed policies that don't require new legislation or funding could have an easier path to implementation through what is likely to be a robust regulatory agenda. President Biden has said that his administration will take a much more active role in pandemic response. One of the first orders of business of the Biden administration was to stop or pause regulations promulgated in the final days of the Trump administration.

The Biden administration will likely use all available regulatory authority for advancing a range of health policy priorities that can be accomplished without an Act of Congress. Biden Administration rollbacks of Trump Administration priorities may include short-term, limited-duration health plans; cuts to ACA navigator funding; 1115 waiver policy, including Medicaid work requirements; 1332 waiver guidance; and weakening of anti-discrimination protections. Use of the Congressional Review Act by Congress regarding regulatory reversals through legislative action is also a prospect, as it was in 2017.

Executive Summary

Our *2021 Healthcare and Life Sciences Investment Outlook*, informed by a survey of healthcare and life sciences executives, analyzes how companies in 10 subsectors have fared during the past unprecedented year of the global pandemic and what we might expect for deal activity in these subsectors in 2021 and beyond. In conducting this annual analysis, we consider the resilience of companies in the subsectors in the face of economic and logistical challenges, as well as how prepared they are for transforming their operations to meet patient needs in both the short and longer term.

Clearly, COVID-19 has been and will continue to be a dominant concern and focus across healthcare and life sciences, although the impact varies by subsector. In our survey, 71 percent of healthcare respondents ranked COVID-19 as one of the top two factors impacting deal activity in 2020, and 53 percent expect it will continue to be a major factor in 2021. For example, hospitals and certain specialty physician practices continue to struggle with fluctuating volumes due to patient reluctance to resume planned or unplanned elective procedures during viral surges.

On the other hand, healthcare IT and risk-based physician practices have sustained less of a negative impact from the pandemic, and many of the assets in these subsectors are experiencing tailwinds. For example, the pandemic has highlighted the advantages of telehealth as a safe and cost-effective mode of care. And there is now a high level of both public and private equity interest in companies in the risk-based physician subsector, which represents a resilient business model that has benefitted from the shift to value.

At the same time, the global life sciences sector continues to play a central role in helping the world move past the pandemic. In 2020, companies that pivoted to COVID-19-related products and services bounced back rapidly and are now attracting more investment interest than those that carried on with "business as usual." Given the need for diagnostics, vaccines, and treatments for COVID-19 and a continuing focus on breakthrough innovations, organizations in the biopharma subsector, in particular, had a stellar year financially, which promises to carry over into 2021.

In this paper, the 10 subsectors on which we focus are divided into three categories based on how companies fared in terms of economic recovery and resilience on the one hand and how focused on innovation and transformation they are on the other.

Highly resilient and sophisticated in terms of innovation and continuous transformation

- Biopharma
- Healthcare IT
- Risk-based physician practices

Fairly resilient to change, but with potential for business transformation

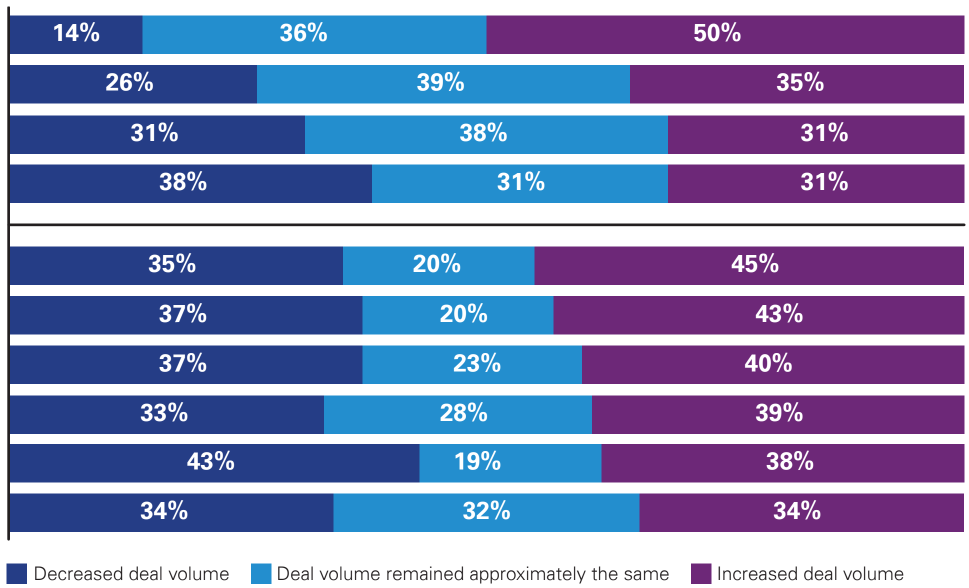
- Behavioral health
- Biopharma services and diagnostic lab services
- Diagnostics manufacturers
- Specialty physician practices
- Home care and hospice

Resilience challenged by economic disruption; need to increase innovation and uncover new areas for growth

- Medical devices
- Hospitals and health systems

In 2020, the deal landscape across healthcare and life sciences varied by subsector, but almost all subsectors ended up with even more deal activity than they had planned at the beginning of the year (Exhibit 2).

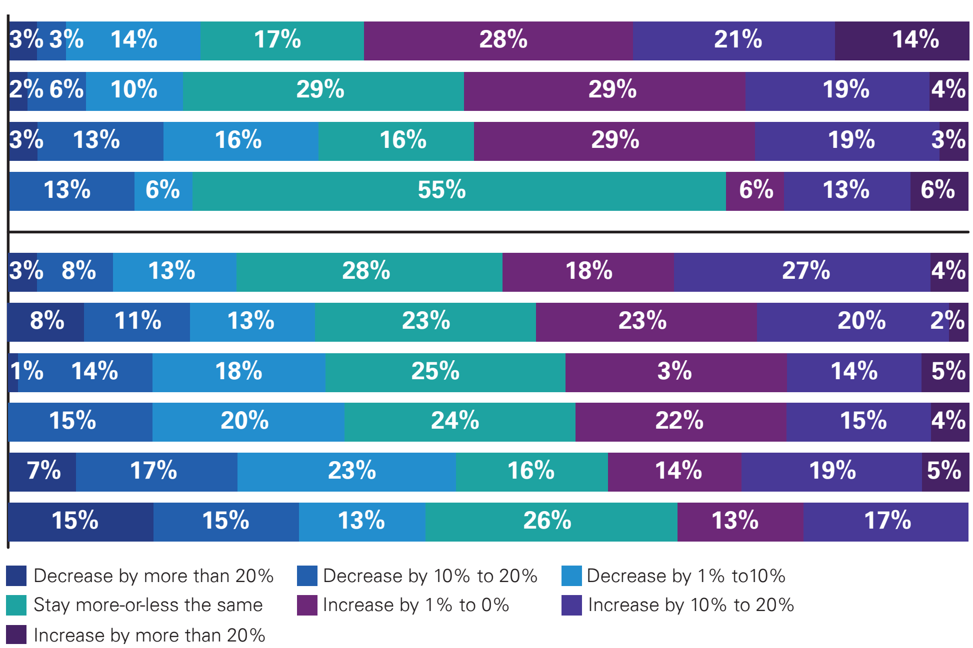
Exhibit 2. Actual 2020 deal activity was higher than early 2020 plans



Source: 2021 healthcare and life sciences investment outlook, KPMG.

In 2021, survey respondents from both healthcare and life sciences agree that the top two avenues for deploying capital will be: (1) investing internally to improve operational efficiency and (2) investing in platform expansion and / or bolt-on acquisitions. There are many signals that deal activity and performance improvement will be strong in 2021, as illustrated by the anticipated increase in valuations in many subsectors from 2020 to 2021 (Exhibit 3) and highlights from our analysis and 2021 healthcare and life sciences investment outlook survey (Exhibit 4).

Exhibit 3. Across many subsectors, valuations are expected to increase from 2020 to 2021



Source: 2021 healthcare and life sciences investment outlook, KPMG.

Exhibit 4. 2020 & 2021 highlights

2020 highlights

- **Biopharma** / life sciences experienced the most active deal market in history with 384 deals in 2020[5]; while total deal value is not reported, 82 percent of pharmaceutical executives saw valuations increase in 2020.
- **Telehealth companies** received the majority of the record $6.5 billion in funding provided to the digital health sector during the first six months of the pandemic.[6]
- **Physician practices** represented an active subsector in 2020: 208 deals involving various models and specialties as of December 2020[7] and robust risk-based physician practice deals initiated by private equity and SPACs.
- Among **diagnostics manufacturers,** the volume of announced or closed acquisitions doubled from 2019 to 2020.[8]
- **Reference lab**-related deal volume remained relatively steady in 2020 compared to 2019,[9] but investor interest in reference labs from non-lab groups increased.
- **Medical device manufacturer** deal volume is perceived to have decreased between 10 percent and 20+ percent this year, according to 69 percent of survey respondents. And yet investment activity picked up toward the end of the year, with 82 transactions in Q4-20.[10]

2021 highlights

- Among **pharma** executives, 71 percent said they will continue to focus on acquiring early-clinical-stage pipeline assets.
- **Telehealth** ranks as the most attractive healthcare IT segment for investment in the next 12-24 months.
- **MSO-managed primary care physician practices** promise to continue to attract significant investor interest due to growth in the population served by Medicare and the expanding share of Medicare Advantage plans.
- **Pharma services and diagnostics labs** are expected to realize increased valuations across all segments of the subsector.
- **Diagnostics-manufacturer** deal volume is expected to increase, with 63 percent of survey respondents saying that moving into COVID-19 testing has allowed their companies to make more deals this year.
- Among **medical device** manufacturing executives, 52 percent will target existing elective procedure technologies for investment.

Our annual *Healthcare and Life Sciences Investment Outlook* is designed to provide insights to investors at the beginning of the investment cycle in each calendar year. This year we are more hopeful than ever that the survey responses and analyses provided in this report will help industry players navigate a very complex marketplace, maximize their resilience to change, and transform to align with the new reality.

[5] Sara Hansard, Covid-19 Surges, Vaccines Drive Pharma, Device Deal Growth, *Bloomberg Law*, December 24, 2020; adapted to include December 2020 data.

[6] Rebecca Pifer, 'Weeks where decades happen': Telehealth 6 months into COVID-19, *Healthcare Dive*, July 27, 2020.

[7] Sara Hansard, Covid-19 Surges, Vaccines Drive Pharma, Device Deal Growth, *Bloomberg Law*, December 24, 2020; adapted to include December 2020 data.

[8] Informa Pharma Intelligence, November 2020.

[9] Ibid

[10] Sara Hansard, Covid-19 Surges, Vaccines Drive Pharma, Device Deal Growth, *Bloomberg Law*, December 24, 2020; adapted to include December 2020 data.

Subsector analyses >

Following is a deeper dive into the 10 subsectors we examine in this report. The subsectors are divided into three categories based on where companies fall within the intersection of 1) resilience in the face of economic disruption and 2) transformation with an eye to the future.

Highly resilient and sophisticated in terms of innovation and continuous transformation

Biopharmaceuticals

Biopharmaceuticals represent one of the few global industries that weathered the pandemic relatively unscathed. As most biopharma players have focused on chronic and life-threatening diseases over the last decade, market demand for the majority of patent-protected, branded, revenue-producing products was largely sustained in 2020.

For some companies, performance was further bolstered by additional government development funding and revenues from COVID-19 therapeutics and vaccines. Overall, the subsector grew by 2.2 percent in 2020, which exceeded the annualized rate in recent years of 1.9 percent.[11]

How biopharmaceuticals fared in 2020

Most active deal market in history:

On the deal front, total deal and acquisition volumes were higher in 2020 than in prior years. In 2020, there were 384 deals announced or closed in pharmaceuticals (under the category of "life sciences and pharmaceuticals") with 113 deals in Q4-20 alone.[12] While deal volume was up significantly compared to prior years, total deal value was nearly flat – even though most deals targeted innovative assets, which have commanded higher valuations in recent years. Our survey found that 81 percent of pharmaceutical executives saw valuations increase in 2020, of which 62 percent said valuations increased more than 10 percent (Exhibit 5).

Deal volume steadily increased over the course of the year, and many were creative, equity-based deals tied to development milestones before further investments are triggered. Additionally, full-company acquisitions were higher than in prior years. (See sidebar.)

In addition to acquisitions, "creative" deals were up as well

Overall, there were 924 biopharma deals in 2020:

96 corporate acquisitions (up from 79 in 2019)

431 licensing deals (up from 342 in 2019)

297 strategic R&D collaborations (up from 145 in 2019)

Sources: Informa; KPMG analysis
*Deal data reflects January 1, 2020 to October 31, 2020 (10 months)

Exhibit 5. Valuations increased significantly in 2020, according to biopharma executives

Source: 2021 healthcare and life sciences investment outlook, KPMG.

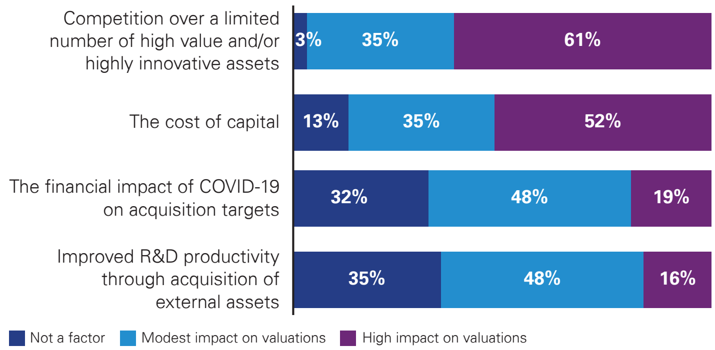
[11] Eva Koronios, Global Pharmaceuticals & Medicine Manufacturing, IBIS World, March 2020.

[12] Sara Hansard, Covid-19 Surges, Vaccines Drive Pharma, Device Deal Growth, *Bloomberg Law*, December 24, 2020.

◆ Focus on early-stage drugs:

The biopharmaceutical subsector is in an unprecedented era of innovation, and competition for next-generation technologies continues to be a major theme in the deal market. For example, cell and gene therapies (CGT) and antibody-drug conjugates (ADC) continue a brisk pace of research and development. There was robust investor interest in these segments of the subsector, even during the economic downturn. High valuations were not a deterrent; in fact, multiple competitors frequently pursued the same targets. Sixty-one percent of our surveyed biopharmaceutical executives believe that competition over a limited number of high-value or highly innovative assets was a major contributor to valuation growth in 2020 (Exhibit 6).

Exhibit 6. Factors impacting 2020 valuations emphasize competition for high-value assets



Source: 2021 healthcare and life sciences investment outlook, KPMG.

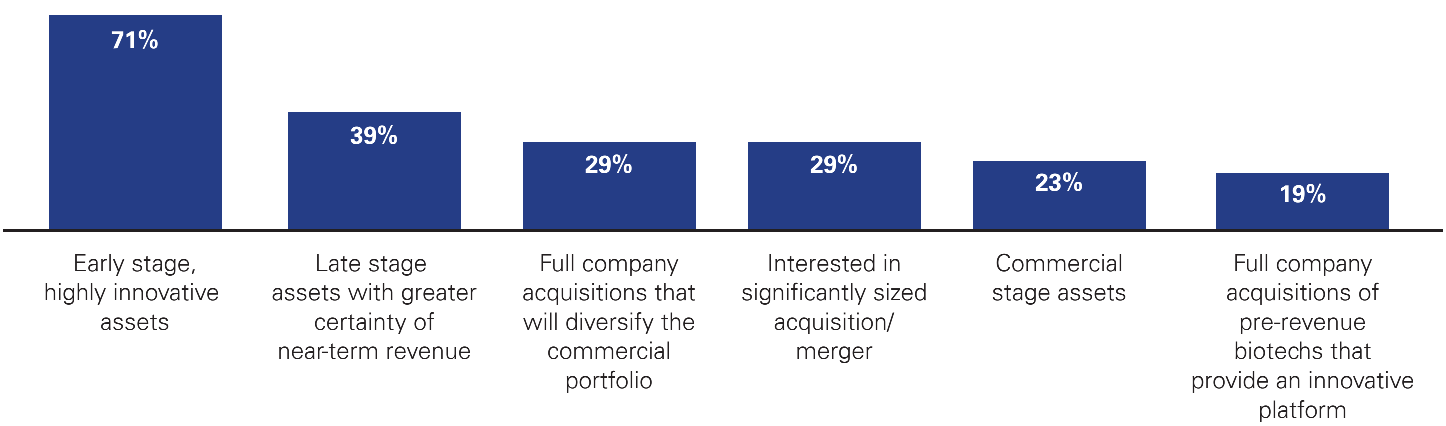
Outlook and investment considerations for 2021

◆ Continued focus on early-stage drugs:

We expect biopharmaceutical companies to continue to focus on acquiring early-clinical-stage pipeline assets. Seventy-one percent of biopharmaceutical executives responding to our survey reported interest in targeting these assets in 2021 (see Exhibit 7).

While scooping up early-stage assets is a risky proposition, the competition for the most compelling technologies that can be first to market has frequently driven investors to pursue pre-clinical and Phase I assets. When assets are potentially curative of ultra-rare, monogenetic diseases, being first to market is essential for justifying the deal investment. This is a notable departure from trends we saw 10 years ago, when large biopharmaceutical companies were primarily interested in assets that had at least achieved Phase II status and viewed being a second- or third-to-market competitor as a reasonable strategy. The types of disease areas the biopharmaceutical subsector has prioritized for deal activity – oncology, immunology, neurology, and infectious disease – have been largely consistent for the past several years and will likely remain so in 2021, according to our survey.

Exhibit 7. 2021 biopharma acquisitions overwhelmingly target early-stage, innovative assets



Source: 2021 healthcare and life sciences investment outlook, KPMG.

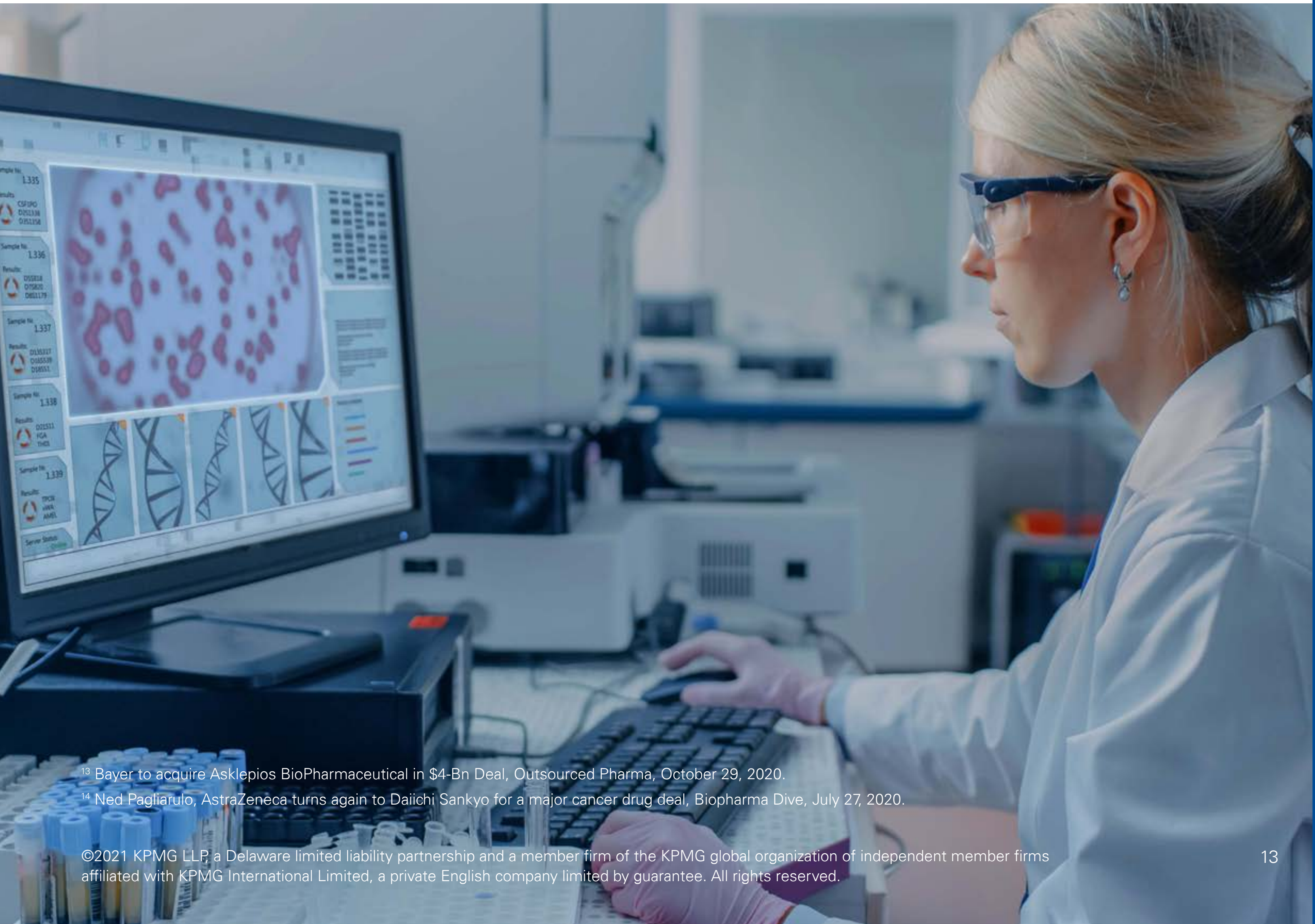
Creative deals continue:

Since biopharma executives in our survey indicate that deals for early-stage assets will be a priority, we expect increasing use of creative deal structures in 2021 and beyond. In other words, while some companies will acquire early-stage biotech companies in certain specialty therapeutic areas, many will mitigate the risk associated with early-stage assets with milestone-based deals. According to our survey, the top three types of investment deals expected by respondents in 2021 are: 1) early-stage, pre-revenue biotech acquisitions, 2) strategic partnerships, and 3) creative equity or financing deals with milestones.

In 2020, there were many examples of creative deal structures designed to de-risk the total investment. For example, Bayer paid upfront consideration of $2 billion for AskBio's cell and gene therapy platform, which will be followed by milestone payments of up to $2 billion based on continued development of the platform.[13] And AstraZeneca agreed to pay $1 billion upfront to Daiichi Sankyo for its antibody drug conjugate targeting multiple tumor types in staged payments: $350 million due upon completion, with $325 million after 12 months and $325 million after 24 months from the effective date of the agreement. AstraZeneca will pay additional conditional amounts up to $1 billion for the successful achievement of regulatory approvals and up to $4 billion for sales-related milestones.[14]

The take-away

Biopharma is clearly undergoing a new period of innovation – from developing COVID-19 vaccines and treatments to cell and gene therapies and antibody-drug conjugates that can change the course of rare diseases. Investors are looking at a variety of ways to play in the subsector with deal structures that include early-stage, pre-revenue biotech acquisitions, strategic partnerships, and creative equity or financing deals with milestones.



[13] Bayer to acquire Asklepios BioPharmaceutical in $4-Bn Deal, Outsourced Pharma, October 29, 2020.
[14] Ned Pagliarulo, AstraZeneca turns again to Daiichi Sankyo for a major cancer drug deal, Biopharma Dive, July 27, 2020.

Regulatory spotlight: Expected evolution of pricing models under Biden administration

Legislative efforts to address prescription drug pricing during the last Congress failed to attract enough bi-partisan support to pass any single approach to drug prices in both the House and Senate. In the absence of Congressional action, the Trump administration generated several regulatory proposals. However, strong industry opposition resulted in successful legal challenges to some of these proposals and an uncertain future for others. The Biden administration may consider continuing or expanding upon some of these regulatory proposals but will likely pull back on others. It is noteworthy that 58 percent of biopharma respondents to our survey believed that a Democratic majority in Congress would act as a "headwind" to deal activity in 2021: Specifically, if Congress were to pass highly restrictive drug-pricing policies, it could make it difficult to justify investments in drugs targeting small populations, which are a major focus of the current deal environment. However, we still anticipate that investors will compete for innovative pipeline assets, just different types at different valuations, given the need to overcome patent expirations and related revenue cliffs.

Reconciliation legislation in the 117th Congress could be a vehicle for prescription drug legislation that was not possible in the 116th Congress. Recent Kaiser Family Foundation monthly tracking polls show that voters from both political parties want Congress to prioritize addressing high drug costs; also the need for budgetary offsets, along with the lower threshold of votes needed for passage, could mean that the conditions are favorable for some form of drug-price legislation to become law through reconciliation legislation. This is a headwind that could become stronger as a reconciliation package is developed in the spring of 2021.

Below are some regulatory actions to watch:

- **Most favored nation pricing:** On November 20, 2020, CMS announced[15] the mandatory, nationwide Most Favored Nation Model[16] to pay no more for high-cost, physician-administered Medicare Part B drugs than the lowest price charged in other similar OECD countries. The model was set to take effect January 1, 2021; however, two federal district courts issued a 14-day temporary restraining order and injunction, respectively, to block implementation of the model until CMS follows requisite regulatory notice and comment procedures.[17] Although the model, if upheld by the courts, may align with the Biden campaign proposal to create a review board that would use international reference prices to help set prices for newly launched specialty drugs,[18] continued support from the Biden administration for implementation of this specific proposal as it is currently written is far from certain given ongoing litigation and a number of practical implementation challenges.[19]

- **Prescription drug rebates:** On November 30, 2020, HHS and OIG issued a final rule[20] to eliminate rebates to middlemen so that price concessions on Medicare Part D prescription drugs could be passed on to patients through discounts at the point of service beginning on January 1, 2022.[21] While generally supported by the biopharmaceutical industry, the proposed rule was subject to intense insurance and pharmacy benefit manager (PBM) scrutiny and opposition. This final rule is already in litigation; moreover, Congress could address issues related to rebates along with other reforms to Medicare Part D.

[15] Centers for Medicare and Medicaid Services, Trump administration announces prescription drug payment model to put American patients first.

[16] Ibid.

[17] Jacquie Lee and Lydia Wheeler, Trump Plan Tying Drug Payments to Foreign Rates Halted Twice, *Bloomberg Law*, December 28, 2020.

[18] Juliette Cubanski, Meredith Freed, Rachel Dolan, and Tricia Neuman, What's the latest on prescription drug proposals from the Trump administration, Congress, and the Biden campaign? KFF, October 6, 2020.

[19] S. Lawrence Kocot, Tracey McCutcheon, and Ross White, Most favored nation drug pricing model final rule, KPMG, November 20, 2020.

[20] Centers for Medicare and Medicaid Services. Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-Of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.

[21] S. Lawrence Kocot, Tracey McCutcheon, and Ross White, Revised Safe Harbor protections for prescription drug rebates, KPMG, December 14, 2020.

Regulatory spotlight: Expected evolution of pricing models under Biden administration (cont.)

- **Importation of prescription drugs:** A Final Rule published in September allows importation program proposals from the states, Indian tribes, and — in certain future circumstances — pharmacists and wholesalers.[22] Although President Biden expressed support for drug reimportation during the campaign, it is not clear whether the Biden administration will embrace this particular approach. Further, early evidence suggests there is little state/manufacturer interest in pursuing such a program, and PhRMA has sued to block the rule.[23]

- **Value-based pricing in Medicaid:** On December 21, 2020, CMS published a final rule to amend the Medicaid Drug Rebate Program statute and add new regulatory provisions to encourage value-based purchasing (VBP) arrangements between drug manufacturers and state Medicaid programs and Medicaid-contracting payors.[24] Most notably, the rule revises the average manufacturer price (AMP) and "best price" reporting requirements in order to provide greater regulatory flexibilities to encourage VBP arrangements. It is unclear how effective this rule will be in promoting these arrangements or how the Biden administration will view this final rule.

- **Lowering patient spending on high-cost conditions:** The Trump administration introduced initiatives to address high-cost conditions, such as lowering diabetes patients' cost-sharing for insulin through 1) an HRSA final rule requiring FQHCs participating in the 340B Drug Pricing Program to provide low-income health center patients access to insulin – as well as injectable epinephrine – at or below the discounted price they have paid under 340B[25] (This rule was suspended for two months while the Biden administration considers it for withdrawal) and 2) a CMMI Part D Senior Savings Model in which Medicare beneficiaries have an increased choice of enhanced alternative Part D plan options that offer lower out-of-pocket costs for insulin.[26] The Biden administration is likely to continue pursuing initiatives and models that target spending on drugs and therapies for high-cost conditions.

[22] S. Lawrence Kocot, Tracey McCutcheon, Ross White, FDA final rule and guidance on importation of prescription drugs, KPMG, October 16, 2020.

[23] PhRMA Litigation Challenging Final Rule on Drug Importation from Canada. November 23, 2020.

[24] Centers for Medicare and Medicaid Services. Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third-Party Liability (TPL) Requirements (CMS 2482-F) Final Reg, December 21, 2020.

[25] Health Resources & Services Administration. Final Rule for the Implementation of Executive Order 13937, Executive Order on Access to Affordable Life-saving Medications, December 2020.

[26] Centers for Medicare and Medicaid Services, Part D Savings Model.

Healthcare IT

The healthcare industry continues its march toward digitalizing operations and finding new ways to capitalize on abundant patient data. This evolution creates demand for a range of technologies: population health management tools, clinical workflow solutions, benefit- and consumer-directed tools, operational and administrative solutions, revenue cycle management tools, electronic health record software, and more. We focus here on two sub-categories within healthcare IT that have gained or sustained notable momentum in 2020:

- Telehealth, which ranked among survey respondents as the most attractive healthcare IT segment for investment in the next 12-24 months, as well as the most disruptive technology trend for the healthcare market in 2021
- The segment of Biopharma IT that focuses on advanced analytics and master data management (MDM) for drug commercialization

How healthcare IT fared in 2020

Overall, healthcare IT (under the category "Healthcare IT and software") had the second highest subsector deal volume in 2020 with 266 deals announced or closed.[27] Q4-20 was the strongest quarter of the year with 96 deals.[28]

Telehealth:

There has been an explosion of telehealth usage since March 2020 when Congress passed the CARES act providing the Secretary of Health and Human Services with broad authority to temporarily waive regulatory requirements and expand telehealth services in the Medicare Program during the COVID-19 public health emergency.[29] Prior to 2020, adoption of telehealth was heavily focused on rural areas and a few medical specialties (e.g., tele-neurology and tele-stroke), and there were restrictions on where and how telehealth services could be provided to patients. After access to in-person treatment was curtailed in March, telehealth adoption soared. Nationwide insurance claims for telehealth rose by 3,552 percent from August 2019 to August 2020.[30] Primary care telehealth visits were highest in major urban areas that were hard hit in the early days of COVID-19 but well prepared for telehealth, i.e., one-third of visits in Phoenix and two-thirds in Boston shifted to virtual modalities.[31]

By the numbers

The largest increases in telehealth use occurred in March and April 2020 with a slight decline from April to June and then a leveling off in the summer.[32] For example, telehealth visits at the University of Pittsburgh Medical Center went from 250 a day in March to 9,500 a day by the end of April. Intermountain Health managed 50,000 telehealth visits a day in March and April, up from only 100 per month before COVID-19.[33]

Telehealth companies received the majority of the record $6.5 billion in funding provided to the digital health sector during the first six months of the pandemic.[34] More specifically, 55 U.S.-based telehealth companies received funding, including platforms like Doctor on Demand and Heartbeat Health. Further, over the course of the year, there were 10 telehealth acquisitions YTD 2020, most notably Teledoc's acquisition of InTouch Health for $600 million in July.[35]

[27] Sara Hansard, Covid-19 Surges, Vaccines Drive Pharma, Device Deal Growth, *Bloomberg Law*, December 24, 2020; adapted to include December 2020 data.

[28] Ibid.

[29] S.L. Kocot, T. McCutcheon, and R. White, Expansion of telehealth in response to COVID-19, KPMG Center for Healthcare Regulatory Insight, May 2020.

[30] Christopher Cheney, Fair Health Monthly Telehealth Regional Tracker, November 6, 2020.

[31] Medicare beneficiary use of telehealth visits: Early data from the start of the COVID-19 pandemic, Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, July 29, 2020.

[32] Christopher Cheney, Fair Health Monthly Telehealth Regional Tracker, November 6, 2020.

[33] Heather Landi, Payers have lowered barriers to telehealth. Will those changes stick? Here's what experts have to say, *Fierce Healthcare*, May 20, 2020.

[34] Rebecca Pifer, Weeks where decades happen: Telehealth 6 months into COVID-19, *Healthcare Dive*, July 27, 2020.

[35] Ibid.

Biopharma IT:

Biopharmaceutical companies are rapidly expanding beyond the $30 billion+ already spent annually on technology for drug commercialization. There is a growing interest in vendors that can offer advanced data analytics and master data management (MDM) for predictive intelligence and scenario planning, driven by: (1) a growing pipeline of targeted drugs (which require advanced analytics to reach very specific patient populations) and (2) the movement toward value-based pricing in biopharmaceuticals. In recent years, payers have focused increasingly on proof of cost-effectiveness and advancement beyond the established standard of care for new drug products.

Outlook and investment considerations for 2021

Telehealth:

The U.S. market for telehealth technology assets is expected to grow seven-fold by 2025, which is equivalent to a five-year compound annual growth rate (CAGR) of 38.2 percent, according to a Frost & Sullivan report from May 2020.[36]

For investors, it is important to expand the view of telehealth beyond the definition of "telemedicine" from the Health Resources and Services Administration's (HRSA) as "the use of electronic information and telecommunication technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration."[38] Instead, investors should consider the larger universe of virtual health technologies, such as artificial intelligence, robotics, wearables, etc. These technologies have the potential to reshape care delivery and create a more efficient and cost-effective healthcare system.

> Some industry advocates estimate that **$250 billion** of U.S. healthcare spending could shift to virtual health, including telemedicine.[37]

Some promising applications include:

- Data-driven patient engagement: digital diagnoses, triage, and routing to the appropriate care pathway using artificial intelligence and robotics
- Synchronous and asynchronous care delivery services, virtual visits, tele-prescribing, and self-management tools, as well as emergency and on-site care delivery
- Home-based patient engagement: management of care transitions, remote patient monitoring (with or without wearables), home-based vitals assessments and medical exams, communications related to care plans and medication adherence, and chronic-care-management tools

[36] Telehealth to experience massive growth with COVID-19 pandemic, says Frost & Sullivan, Frost & Sullivan, May 13, 2020.

[37] Tanya Albert Henry, After COVID-19, $250 billion in care could shift to telehealth, American Medical Association, June 18, 2020.

[38] Medicare beneficiary use of telehealth visits: Early data from the start of the COVID-19 pandemic, Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, July 29, 2020.

Regulatory spotlight: Will COVID-19 waivers for telehealth be extended?

The permanence of relaxed telehealth requirements – including extension of waivers and other flexibilities – will depend on CMS's assessment of telehealth usage data and the potential cost/benefit to the Medicare program, as well as a corresponding act of Congress, to permanently expand telehealth services in Medicare. As the Biden Administration considers if and how to extend some of the telehealth flexibilities instituted during the public health emergency, CMS will likely consider some of the following issues: quality and cost of care; payment parity between in-person and telehealth care; instances of fraud, waste, and abuse; and whether alternative payment models should be given greater flexibility than fee-for-service Medicare. Two of the most significant stipulations that would allow continued expansion of telehealth would require changes to the Social Security Act: (1) the geographic requirement, i.e., that the person receiving a service lives in a designated rural area, and (2) the "originating site requirement," i.e., that patients generally leave their homes and go to a clinic, hospital, or other medical facility for the telehealth service. Despite the statutory limitations, CMS could expand access to certain qualifying telehealth services through annual payment rules (e.g., Physician Fee Schedule) or states could relax restrictions on state licensure, permitting physicians to provide telehealth services across state lines.[39]

Biopharma IT:

We expect the drug commercialization segment of biopharma IT to continue to consolidate, especially as biopharma manufacturers shift from outsourcing discrete projects to engaging more diversified providers as one-stop shops. There are several types of commercialization services: consulting companies, marketing generalists, focused specialists, diversified biopharma services providers, and multi-service communications specialists (see the "Biopharma services and diagnostics labs services section" on page 28.). Here we focus on the emerging category of companies that offer advanced analytics and master data management solutions. For example:

- **Panalgo**, formerly BHE, has expanded its data analytics offerings to encompass real-world evidence, outcomes research, epidemiology data, safety data, commercial analytics, and research and development findings.[40]
- **Axtria** is a leading provider of cloud-based data analytics solutions with a platform deploying AI and machine learning to drive biopharma companies' sales growth and improve patient outcomes.[41]
- **Indegene Healthcare**, a fast-growing digital and AI-based biopharma commercialization company, has announced that it plans to acquire companies that provide commercial, medical/regulatory, and medical communications services in the $4 million to $40 million revenue range, including startups.[42] Current plans will build upon several years of acquisitions, including the 2019 takeover of DT Consulting.
- **Komodo Health**, backed by venture capitalists Andreessen Horowitz and Oak HC/FT, is a rapidly growing biopharma analytics vendor that is well known for its Healthcare Map, which encompasses a vertical technology stack of data, data management, and analytics.[43]

The take-away

Using telehealth technologies to continue treating patients during the pandemic will likely continue in some form for the foreseeable future. Biopharma IT is a growing and diversifying area that is helping drug makers not only evolve in their communications with patients and physicians, but also pursue virtual clinical trials, precision medicine, and more. Taking a broader look at the spectrum of healthcare IT offerings, there are technology implementations – from migrating data to the Cloud to advanced uses of predictive analytics and AI – that will help the healthcare industry offer better customer experiences, achieve economic efficiencies, and streamline the continuum of care through digitalization of the entire healthcare ecosystem.

[39] S.L. Kocot, T. McCutcheon, and R. White, Medicare telehealth and COVID-19: Opportunities and challenges for extending Medicare telehealth flexibilities beyond COVID-19 declarations, KPMG Center for Healthcare Regulatory Insight, June 2020.

[40] BHE announces rebrand t.o Panalgo, continues its mission of leadership in analytics software for healthcare, Panalgo press release, July 27, 2020.

[41] Axtria research paper explores COVID-19's pharmaceutical impact, GlobeNewswire, April 6, 2020.

[42] Indegene on the prowl for global acquisitions, Indegene press release, August 12, 2020.

[43] Komodo Health secures $50 Million in Series C funding led by Andreessen Horowitz, joined by Oak HC/FT, Komodo Health press release, January 8, 2020.

Risk-based physician practices

Even as patients avoided all but the most critical medical appointments during COVID-19, payments to capitated physician practices remained on schedule. As a result, risk-based physician practice models provided more secure financial arrangements for physicians than practices that rely exclusively on fee-for-service payments. The evolution toward value-based care was already in motion prior to the pandemic, but current market dynamics may make alternative payment models (APMs) more attractive to physicians who are wary of fee-for-service volatility. Moreover, risk-based models may gain even further momentum in the coming years as the Biden administration focuses on expansion of new models under the Affordable Care Act (ACA).

In the risk-bearing arena, a variety of APMs have been adopted, chiefly by primary care providers (PCPs). Currently, more than one-third of all U.S. healthcare payments flow through APMs, according to the Healthcare Payment Learning and Action Network.[44] APM models include alternative fee-for-service architectures, population-based payments, Medicare models outside of Medicare Advantage (MA), direct contracting, and many specialty-focused models.

For the purposes of this paper, we focus on two types of models:

- **MSO-managed primary care physician practices:** As physician practices with corporate or private equity ownership, these practices typically focus on Medicare Advantage or other risk-based arrangements with health plans, often under management services organization (MSO) arrangements. These models have been rapidly gaining popularity, which we expect will continue.
- **Health plan-owned physician practices:** Mid- and large-sized health plans are building risk-based programs to effectively manage their members or looking to acquire risk-based physician practices to serve multiple payers' members as a revenue-diversification play (or both). Health plans have been acquiring physician practices for several years and are typically focused on transactions that allow them to improve access, manage utilization and unit cost of care, and increase services and capabilities provided within a network.

How risk-based physician practices fared in 2020

MSO-managed primary care physician practices:

The degree to which MSO-managed primary care physician practices have been able to assume risk has been driven, at least in part, by continued growth in Medicare and by the continued expansion of the share of Medicare represented by Medicare Advantage (MA) plans. As of December 2020, the MA population totaled 24.8 million lives, which represents 39.5 percent of the overall Medicare population.[45] Analysts project that the percentage of Medicare represented by MA will reach nearly 50 percent by 2030.[46] MA platforms typically have compensation models where employed physicians care for attributed, capitated lives or where the entities sell their MSO capabilities to other groups, which take on risk (including capabilities related to analytics and care management). There are also models where groups share in profits related to managing care for members.

Some notable deals in 2020 that highlight these models include: Sun Capital's acquisition of Miami Beach Medical Group, the second largest independent provider of capitated primary care services to MA members in South Florida, and Arsenal Capital Partners' acquisition of Best Value Healthcare, a population-health-focused provider in the Tampa Bay area.[47]

[44] 2020 APM Measurement Effort, Healthcare Payment Learning and Action Network.

[45] Centers for Medicare and Medicaid Services. Monthly Enrollment by State 2020-12.

[46] Meredith Freed, Anthony Damico, and Tricia Neuman, A Dozen Facts About Medicare Advantage in 2020, KFF, April 22, 2020.

[47] Arsenal Capital Partners acquires Best Value Healthcare, PR Newswire, November 17, 2020.

Another investment trend in 2020 was rising interest in the sector by special purpose acquisition company (SPAC) investors. In November, Cano Health, a value-based healthcare platform with more than 500 PCPs across several states and Puerto Rico, announced it would go public via a SPAC transaction.[48] And insurance start-up Clover Health had an IPO via a SPAC backed by Social Capital in October.[49]

Health plan-owned physician practices:

The trend toward health plans acquiring providers continued to grow in 2020, with increases in both first-time acquisitions and health plan/provider networks continuing to expand their capabilities through acquisitions. Both Optum and Humana have made acquisitions in areas such as urgent care, ambulatory surgery centers (ASCs), and post-acute care. These deals are aimed at management of member care and/or taking on risk for other payors. For example, Optum has integrated its practices with MedExpress, Surgical Care Affiliates, and NaviHealth. Humana has integrated its groups with Curo Health Services and Kindred Healthcare, a post-acute provider purchased in conjunction with two private equity firms.[50] These models continue to be attractive to investors since they allow health plans to realize more value from capitated arrangements, increase profitably, and enjoy exemption from medical-loss-ratio (MLR) reporting requirements.

Outlook and investment considerations for 2021

The current environment offers several different opportunities for investment across the spectrum of risk-based offerings.

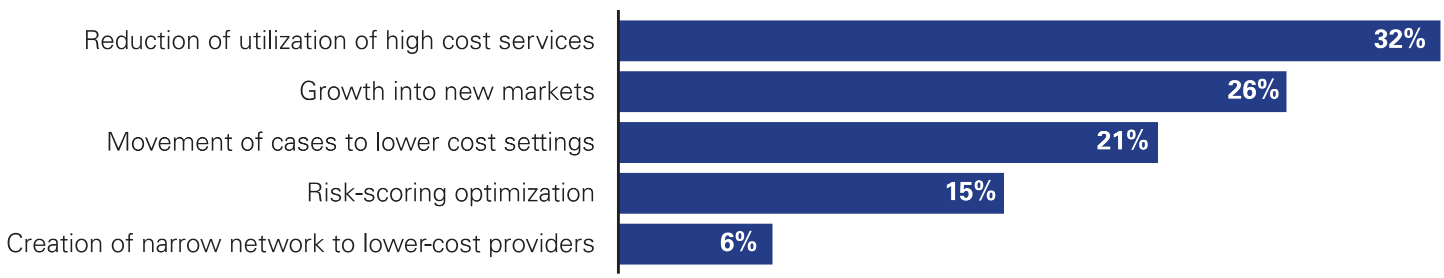
Horizontal vs. vertical integration:

Among both MSO-managed practices and health-plan-owned practices, most will go deeper into their current markets with horizontal integration deals, as evidenced by the fact that 60 percent of survey respondents said that their top investment priority for 2021 was one of the following:

- *Acquiring assets required for value-based payment initiatives:* These are foundational capabilities that allow practices to achieve a lower cost of care per patient.
- *Acquiring to expand the provider network:* These deals increase density in the market, i.e., adding more PCPs to allow the practice to manage a larger portion of the patient population. This trend was supported by survey respondents who said the primary deal thesis in this subsector was reducing the utilization of high-cost services (Exhibit 8).

While most risk-based physician practices will pursue horizontal integration, some practices – particularly those that have refined their models in their own markets – will focus more on vertical integration, i.e., expanding into new markets and integrating with specialists (Exhibit 8). Among PCPs that are focused on risk, most survey respondents cited behavioral health, cardiology, urgent care, and orthopedics as the top areas necessary for success in risk agreements. Forty-six percent of respondents ranked behavioral health as their top specialty for future investment.

Exhibit 8. Risk-based physician practice deal theses



Source: 2021 healthcare and life sciences investment outlook, KPMG.

[48] Cano Health to list via $4.4 billion merger with Barry Sternlicht-backed SPAC, Reuters, November 12, 2020.

[49] Clover Health to go public via $3.7 billion deal with Social Capital, Reuters, October 6, 2020.

[50] Randi Seigel and Annie Miyazaki-Grant, Navigating Compliance Challenges for Integrated Health Plan-Provider Systems, Healthcare Compliance Association, January 27, 2020.

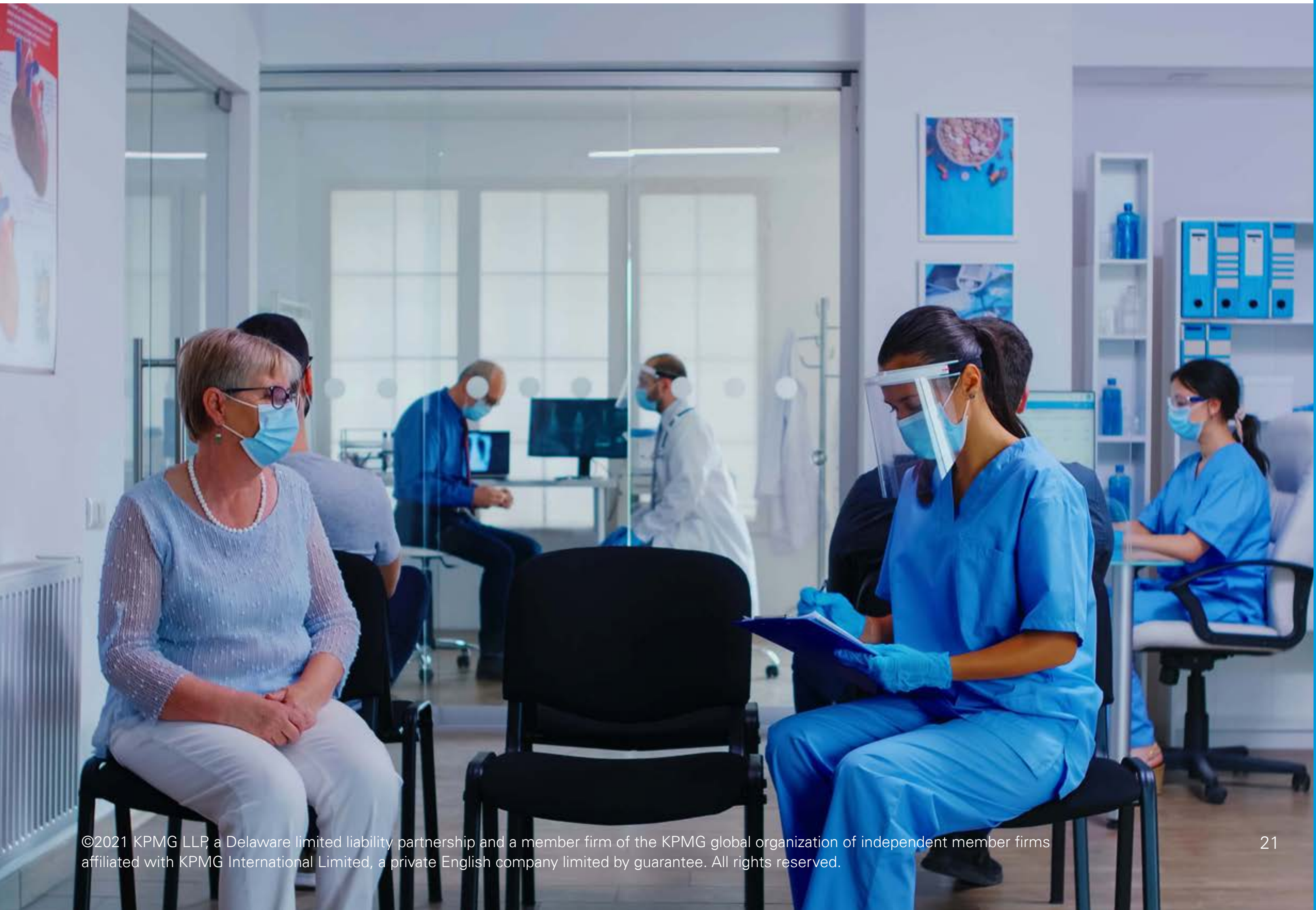
Qualities of leading risk-based physician practices

When evaluating risk-based physician practices, investors often evaluate whether the practice has:

- Access to growing MA membership pools and the capacity to take on new patients
- Optimized risk scores and capitated payments via comprehensive capture of all a patient's medical conditions
- Streamlined provider productivity and compensation associated with targeted panel sizes
- Sourced and deployed capabilities required for effective medical cost management and appropriate site-of-care utilization, including advanced IT capabilities to track more vulnerable patients and standardize how data is pulled from EHRs and claims
- Realization of new revenue streams through commercialization to other risk-bearing providers of managed-services models or medical-cost-management capabilities

The take-away

There are numerous opportunities for investment in risk-based physician practices, although optimizing value in this subsector can be difficult. Value can be driven by controlling medical costs, combined with expanding patient/member pools. However, many organizations have found expansion to be the easier of the two options and have, therefore, focused their efforts on further penetration of current markets or growth into new markets.



Fairly resilient to change, but with potential for business transformation

Behavioral Health

In the behavioral health subsector, mental health and substance abuse providers continue to be very attractive to investors. Demand for services has been rising in recent years, driven by the opioid epidemic, widening income inequality, a diminished social safety net, and other societal problems such as the potentially toxic effects of social media, all of which have worsened during the pandemic. Although the stigma about mental health and substance abuse treatment has diminished, there are still supply-side problems, including a lack of qualified personnel, despite added funding through COVID-19 stimulus. We expect investment in technology-enabled behavioral health services and innovative niche providers, as well as rollups of outpatient mental health providers into larger, more diversified entities, will continue to drive growth in the subsector.

How behavioral health fared in 2020

Rapidly increasing demand:

The COVID-19 outbreak has exacerbated long-standing unmet needs for mental health and substance abuse treatment across the nation. As a result, demand for integrated behavioral health services is expected to continue to increase in the coming years. Consider the following:

- In a July 2020 survey, 30 percent of adults reported symptoms of depression and 36 percent said they were being treated for anxiety disorders.[51] A year earlier, only 6.6 percent of people reported depression symptoms and 8.2 percent reported symptoms of anxiety disorders.[52] By November of 2020, 43 percent of Americans showed signs of clinical depression or anxiety, according to census data.[53]
- Only 3.7 million, or 18.2 percent, of the 20.3 million Americans with a substance use disorder received treatment in 2020.[54] As a result, overdose rates are on the rise: the CDC reports more than 80,000 drug overdose deaths between June 2019 and May 2020[55] with the largest increase between March and May 2020.[56] A recent survey concludes that there has been a 16 percent increase in overdose submissions since stay-at-home orders began.[57]
- Opioid use (heroin or prescription pain relievers) accounted for an estimated 20 percent of adult illicit drug use in 2020.[58] Although the opioid epidemic is no longer a regular focus of the news media, misuse of opioids is still leading to more deaths than ever with current estimates from the CDC stating that, on average, 130 Americans die every day from an opioid overdose.[59]

Increased demand for services will create challenges since the supply of qualified and specialized mental health providers remains limited. Our survey respondents indicated that the short supply of psychiatrists could be the greatest limitation on growth and investment in the behavioral health subsector. While increasing reliance on other types of behavioral health providers – clinical psychologists, mental health and substance abuse counselors, social workers, etc. – is expected to fill some of the gap, we expect demand to continue to outstrip supply.

> "98 percent of survey respondents said the opioid crisis and increased focus on addressing substance abuse will maintain or increase deal volume in 2021 and beyond."

[51] Bailey Bryant, Behavioral health deal values up 900% quarter-over-quarter, *Behavioral Health Business*, August 10, 2020.

[52] Ibid.

[53] William Wan, Pandemic relief bill delivers $4.25 billion for mental health services, *Washington Post*, December 22, 2020.

[54] Key substance use and mental health indicators in the united states 2020, SAMHSA, 2020.

[55] Brianna Ehley, CDC: Annual drug overdoses could top 81,000, *Politico*, December 17, 2020.

[56] William Wan, Pandemic relief bill delivers $4.25 billion for mental health services, *Washington Post*, December 22, 2020.

[57] Charles Rhyee, James Auh, Calvin Sternick, and Gwen Shi, Initiate outperform: Getting ONTRAK in behavioral health, Cowen, July 16, 2020.

[58] Kevin Kennedy, Mental Health & Substance Abuse Clinics in the US: Mental wellness: Increased health insurance coverage is expected to boost demand for the industry, IBIS World, October 2020.

[59] Ibid

Pivot to teletherapy:

Although underserved populations lacked access to services in 2020, the pivot to teletherapy services during the public health emergency allowed a significant number of mental health and substance abuse patients to continue receiving treatment despite social distancing guidelines. Investors quickly took note: In the first half of 2020, digital behavioral health startups received $588 million in funding, which is more than this segment typically receives over the course of a year.[60]

Of the $5.4 billion in funding raised by all U.S. digital health companies, 11 percent went to behavioral health startups. One example is Lyra Health, a platform for customized mental health services offered through employers such as Starbucks and Uber.[61] Lyra has received $292 million in funding to date and has a total valuation of $1 billion. The funds will be used to expand and diversify Lyra's provider network and continue to grow Lyra Blended Care, which pairs video therapy sessions with personalized cognitive behavioral therapy (CBT) exercises, the company says.

Deal landscape:

M&A interest in outpatient behavioral health, especially psychiatric care, gained significant traction in 2020 as several businesses in the subsector obtained the necessary scale to transact. One such business, LifeStance Health, received a $1.2 billion investment from TPG Capital in April 2020,[62] reflecting the market's interest in outpatient psychiatric care.

Outlook and investment considerations for 2021

Meeting growing demand:

Post COVID-19, we expect unmet needs for mental health and substance abuse services to drive subsector growth at an annualized rate of 3.3 percent through 2025. Our survey respondents indicated that substance abuse and outpatient psychiatric care would be the biggest drivers of growth in patient demand in 2021.

Continuing use of teletherapy:

Although there are concerns about shortages of qualified psychiatrists and therapists in certain geographic areas and among some populations,[63] access can be addressed to some degree by providing more teletherapy services and increasing the use of other remote-delivery technologies, such as text messages to supplement in-person therapy and online support groups. Of course, the continuing use of teletherapy depends on CMS continuing to offer waivers so that services can be delivered to patients across state lines. There are several issues that CMS may have to consider, including where patients are referred for emergency treatment if their therapist resides in a different geography.

Although teletherapy will not solve all challenges in behavioral health, it is seen as an important advance in patient access, and investors are recognizing its potential. Seventy-seven percent of respondents said they expect growing use of virtual care technologies to increase deal volume in the behavioral health subsector in 2021.

Deal landscape:

Nearly 60 percent of behavioral health survey respondents said that their top investment priority was either acquiring new capabilities or acquiring providers and practices to expand provider networks. Market concentration has slightly increased over the past few years and we expect consolidation in this fragmented subsector to continue. For example, according to our survey, both risk-based and non-risk-based physician practices are interested in investing in behavioral health as part of practice rollups, which will help organizations scale, improve outcomes, and command better reimbursement rates as the healthcare industry continues to move toward value-based care. Especially for risk-based practices, behavioral health roll-ups are viewed as beneficial in the effort to take on risk and control healthcare spend for the populations they serve.

[60] Heather Landi, Digital behavioral health startups scored $588M in funding amid COVID-19 pandemic, *Fierce Healthcare*, July 6, 2020.

[61] Heather Landi, Lyra Health gains unicorn status as demand for teletherapy soars, *Fierce Healthcare*, August 26, 2020.

[62] Bailey Bryant, Behavioral health deal values up 900% quarter-over-quarter, *Behavioral Health Business*, August 10, 2020.

[63] Lists of Designated Primary Medical Care, Mental Health, and Dental Health Professional Shortage Areas, *Federal Register*, June 15, 2020.

The take-away

Although demand for mental health and substance abuse treatment has been on the rise in recent years, the pandemic has multiplied the need. With a growing shortage of qualified providers, behavioral health companies will need to pursue a variety of strategies to meet patient needs, including relying more on telehealth services. It is also likely that many players will look to consolidation to increase scale to align with demand.

Regulatory spotlight: Improving patient access

In December 2020 Congress earmarked nearly $4.25 billion for mental health and substance use disorders as part of the $900 billion stimulus package.[64] This comes on top of the relief funds provided for behavioral health through the CARES Act last May.[65] Nonetheless, many industry experts believe that federal funds for behavioral health still fall significantly short of what is needed to keep some struggling organizations afloat.

We expect pressure for mental health parity to continue, which will presumably drive some increase in access, although for now payer compliance is far from universal. At the same time, there may be some progress on issues of access due to the increasing amount of behavioral health revenue that is generated through Medicare, Medicaid, and other government programs – currently at 47.5 percent and expected to continue to grow at an annualized rate of 4.2 percent over the next five years.[66]

[64] William Wan, Pandemic relief bill delivers $4.25 billion for mental health services, *Washington Post*, December 22, 2020.

[65] COVID-19 Response CARES Act Includes $425 Million to Boost Mental Health and Substance Use Disorder Care in the Communities, National Association of State Mental Health Program Directors.

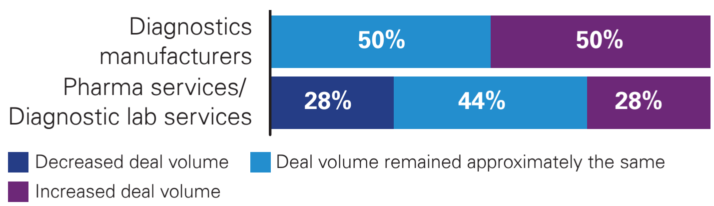
[66] Kevin Kennedy, Mental Health & Substance Abuse Clinics in the US: Mental wellness: Increased health insurance coverage is expected to boost demand for the industry, IBIS World, October 2020.

Fairly resilient to change, but with potential for business transformation

Biopharma services and diagnostic lab services

COVID-19 served as a catalyst for some long-awaited changes in the biopharma services and diagnostic labs subsectors, including accelerating the shift to virtual clinical trials and diversification of lab offerings. Investors clearly recognize the growth potential of organizations in this subsector: Private equity survey respondents ranked the subsector in the top two for likely investment in 2021. Further, compared to expectations on January 1, 2020, the majority of respondents saw either no impact or an increase in their deal activity in the subsector over the course of the year, despite the pandemic (Exhibit 9).

Exhibit 9. Despite the pandemic, PE deal plans increased or stayed steady throughout 2020



Source: 2021 healthcare and life sciences investment outlook, KPMG.

How biopharma services and diagnostic lab services fared in 2020

Biopharma services

◆ Contract research organizations:

Despite some pauses in drug development and approvals in 2020, the biopharma services subsector is still on track to reach almost $64 billion by 2024, up from a little over $43 billion in 2019.[67] Growth (8.2 percent CAGR) will be driven by increasing demand for: 1) specialized product development and formulation capabilities, 2) innovative bioprocessing capabilities, 3) remote monitoring and other virtual clinical trial capabilities, 4) new advanced analytics across the R&D continuum, and 5) novel biomarkers.[68]

These shifts have been in progress for some time; even before COVID-19, contract research organizations (CROs) were in demand to support the development of innovative drugs and reduce patient burden during clinical trials. During COVID-19, CROs faced both the need to invest in remote clinical trial capabilities to sustain operations and a significant increase in demand to find virtual ways to collect patient data. These trends were furthered by the FDA's recommendation that assessments and local bio-sample collection be conducted virtually when possible.[69]

◆ Medical communications firms:

During the pandemic, there has been an increased need for virtual interactions with physicians and a greater emphasis on using digital marketing channels. Digital marketing assets have become a greater focus for private equity investors as they see the growing demand for entities that can help the biopharmaceutical subsector transition toward true omni-channel capabilities. Investors are targeting companies that are able to push out campaigns through different media channels, and also collect and analyze consumer and healthcare provider engagement information to gain insight into campaign effectiveness or the need to redesign campaigns to improve local market engagement. The range of digital campaigns is extensive and some of these emerging companies have different strengths, e.g., consumer marketing and brand awareness vs. medical education and disease awareness.

[67] Ben Adams, CRO market to recover, using 'hybrid trials,' with revenue hitting $64B by 2024: report, *Fierce Biotech*, September 8, 2020.

[68] Ibid.

[69] FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency. Guidance for Industry, Investigators, and Institutional Review Boards. 1–35 (Administration UDoHaHSFaD, 2020).

Diagnostic lab services:

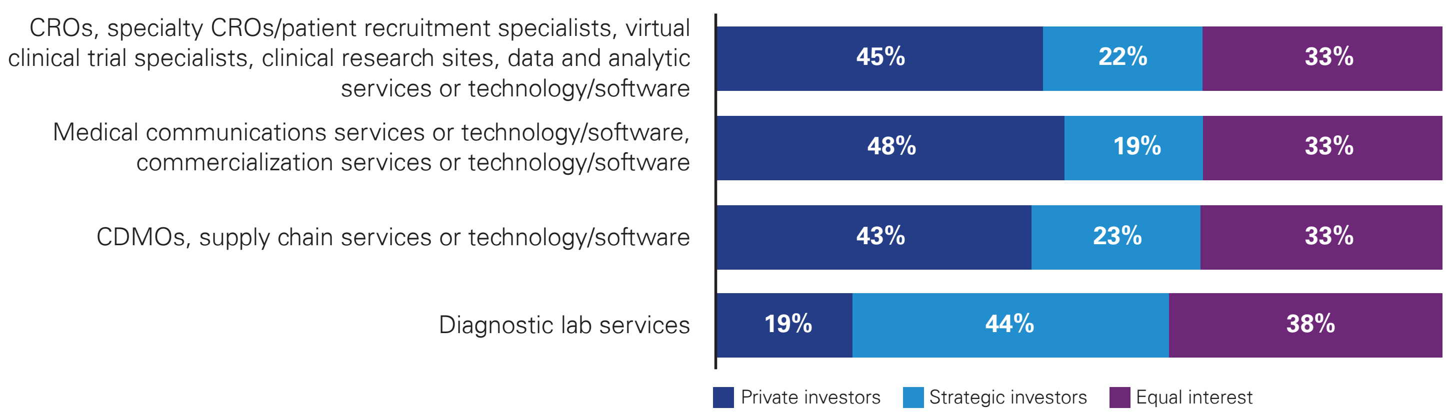
During the early months of the pandemic, patient volume for routine testing fell precipitously, with some labs losing 75 percent of their basic test volume.[70] Many labs quickly shifted some of their volume or built capacity for COVID-19 testing both to meet patient needs and to protect their businesses. These labs offset some of their losses, and core businesses recovered, as patients returned to routine testing after the first surge. Overall, revenues for the subsector are expected to come in at 6.8 percent higher in 2020 than in 2019.[71]

Transaction volumes for reference-lab assets remained relatively steady in 2020, with acquirers focusing on diversification and innovation. Notable 2020 deals included the acquisition of Thrive Earlier Detection by Exact Sciences (a ~$2.15 billion deal for liquid-biopsy capabilities)[72] and the acquisition of ArcherDx by Invitae (~$1.4 billion for kit-based expansion).[73] The volume of investor group and CRO deals (both acquisitions and increased investment) rose 14 percent through November 2020 over 2019.[74] These investors expect COVID-19 testing to drive lab volume and revenue in the next year or two, even after vaccines are more widely available. For example, Liang Yaoming and other investors increased their stake in Guangzhou KingMed Diagnostics by 5 percent or $100 million in April 2020[75] as the lab reached the 2 million test milestone.[76] On the other hand, fewer existing labs acquired new labs as they focused investment dollars and resources on developing COVID-19 testing capabilities. Specifically, between YTD 2020 vs. 2019, there were ~6 percent fewer lab consolidation deals and 9 percent fewer acquisitions of adjacent assets by labs.[77]

Outlook and investment considerations for 2021

Although investment is likely to be robust in 2021 across biopharma services and diagnostic labs, we expect to see some variations in types of investors. Private equity is expected to focus more on specialty CROs, specialized data and analytic services, contract development and manufacturing organizations (CDMOs), and digital communications services, while strategic investors are expected to focus more on diagnostic lab services (Exhibit 10).

Exhibit 10. PE focused on pharma services; strategic investors focused on diagnostic labs.



Source: 2021 healthcare and life sciences investment outlook, KPMG.

[70] KPMG personal communications with diagnostic lab-based clients, December 2020

[71] Jack Curran, Diagnostic & Medical Laboratories in the US, IBIS World, June 2020.

[72] Amirah Al Idris, Exact Sciences snaps up liquid biopsy company Thrive in $2.15B deal, *Fierce Biotech*, October 27, 2020.

[73] Jensen Werley, Invitae completes its $1.4B acquisition of Boulder-based ArcherDX, BizJournals, October 5, 2020.

[74] Informa Pharma Intelligence (2021).

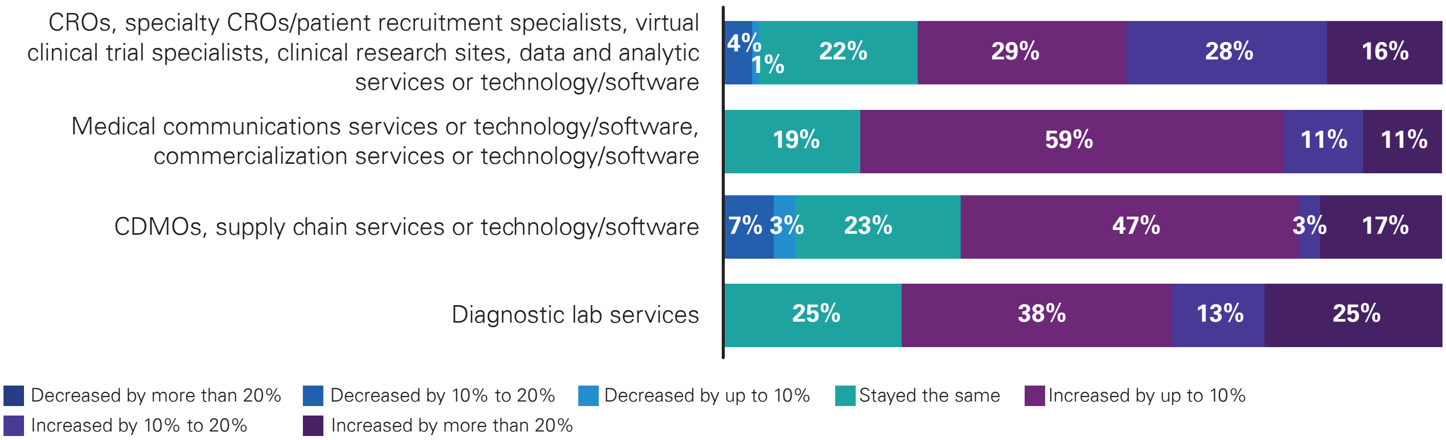
[75] Refinitiv, 2020.

[76] Xinhua Headlines: China's Guangdong expands nucleic acid testing to include everyone in need, KingMed Diagnostics press release, May 18, 2020.

[77] Refinitiv, 2020.

Valuations continued to increase in 2020 and survey respondents largely agree that valuations will likely continue to grow in all segments of biopharma services and diagnostic labs in 2021, with potential increases of 10 to 20 percent or more. Overall, 82 percent of respondents expect to see investment in medical communications companies increase, while more than 70 percent expect significant investment in both the CRO and diagnostic labs segments (Exhibit 11).

Exhibit 11. Highest investment increases expected in medical communications, followed by CROs and labs



Source: 2021 healthcare and life sciences investment outlook, KPMG.

Biopharma Services

◆ CROs:

Survey respondents expect considerable activity in this segment of the subsector. Investor interest aligns with the fact that the biopharma services subsector will continue to grow, driven by a multitude of mega trends, including:

1. Increasing industry focus on cell and gene therapies (i.e., nucleic acid-based therapies), which require significant investment to address manufacturing capacity and capabilities, as well as supply chain capabilities to support development efforts

2. A growing pipeline of highly specialized oncology assets (e.g., antibody drug conjugates), which require biopharma services for support

3. The accelerating shift to virtual clinical trials to expand patient recruitment capabilities and reduce travel barriers. Advances in remote monitoring will require CROs to scale and diversify their capabilities across multiple functions, such as Institutional Review Board (IRB) management, adverse event tracking, and patient compliance monitoring

4. Growing demand for faster development/manufacturing of COVID-19 vaccines and therapeutics, which requires biopharma services support for platform development

Focus on cell and gene therapy: Deep freeze technology investments

As cell and gene therapy R&D grows, biopharma services companies are investing in deep freeze technology manufacturers to ensure that they have access to ultra-cold supply chains for transferring drug components and drugs themselves. While in some cases CDMOs and distributors are building freezer farms outright, they are mostly pursuing strategic partnerships and acquisitions. For example, Cryoport, a major logistics provider to regenerative medicine manufacturers, used an infusion of cash from Blackstone to acquire MVE Biological Solutions in order to gain access to its dewar and cryogenic freezer supplies.[78]

[78] Cryoport gobbles up MVE Biological Solutions, extending its deep-frozen scope, *Pharmaceutical Commerce*, August 25, 2020.

Medical communications:

Consolidation in the medical communications segment of biopharma services will likely continue and accelerate in 2021 as biopharmaceutical manufacturers increasingly seek one-stop shopping for communications services. In 2020, for example, the international healthcare and communications group Huntsworth agreed to acquire Nucleus Global, one of the world's largest medical specialist communications groups.[79] The scientific communications company Envision Pharma Group acquired Two Labs, which provides integrated and customized commercial communications services to pharmaceutical and biotechnology companies.[80] And the combined contract commercial organization/CRO Syneos Health acquired the full-service CRO Synteract.[81]

Diagnostic lab services:

Bouncing back from the loss of patient volumes earlier in the pandemic, many clinical reference labs have returned to pre-pandemic levels, as many patients could no longer delay routine health checkups or treatment for chronic health conditions. However, given the global surge in late 2020, we expect a corresponding decline in routine testing services in early 2021. At the same time, labs that were able to significantly increase COVID-19 testing capacity and reduce turn-around time will likely see another spike in demand. Quest Diagnostics, which has ramped up COVID-19 testing capacity to more than 200,000 tests per day, is one of the labs forecasting higher overall revenue targets for 2021 than they had before COVID-19.[82]

As we look past the pandemic, subsector revenue is expected to grow at an annualized rate of 2.1 percent per year to $57.8 billion by 2025.[83] In 2021, large reference labs such as Bioreference, Labcorp, and Quest, as well as some smaller labs that expanded into COVID-19 testing and have new cash reserves, are expected to buy new assets and diversify so that they are in a stronger position when COVID-19 testing demand wanes.[84]

The take-away

One positive outgrowth of the COVID-19 pandemic is that it accelerated some overdue changes across the healthcare and life sciences industry. In the biopharma services and diagnostic lab services subsector, while there is still the need for further transformation, 2020 brought a more definitive shift to virtual clinical trials and diversification of lab offerings that promise to last for years to come. The pandemic had either no impact or a positive impact on investment plans in the subsector in 2020, and activity should be robust going forward as the subsector ranked in the top two for PE investor interest in 2021.

[79] Huntsworth expands global health network with Nucleus acquisition, Huntworth press release, November 6, 2020.

[80] Envision Pharma Group acquires Two Labs to advance its position as a global strategic partner to pharma and create a unique and unrivaled launch excellence offering, Businesswire, November 12, 2020.

[81] Syneos Health completes acquisition of Synteract, Syneos press release, December 10, 2020.

[82] Quest Diagnostics Quarterly Report, October 23, 2020.

[83] Jack Curran, Diagnostic & Medical Laboratories in the US, IBIS World, June 2020.

[84] Informa Pharma Intelligence (2021).

Fairly resilient to change, but with potential for business transformation

Diagnostics manufacturers

While the demand for routine diagnostic test platforms and reagents was depressed for months in 2020, diagnostics manufacturers that pivoted to COVID-19 testing thrived. These companies enjoyed rising revenue and valuations since last March, helping revive their interest in M&A. COVID-19 also created the need for more near-to-patient testing methods as people were advised to (or preferred to) stay home. In addition, companies that offer innovations such as point-of care testing, direct-to-consumer testing, and liquid biopsy, as well as other less-invasive sampling options for COVID-19 and other diseases, all had higher valuations.

How diagnostics manufacturers fared in 2020

Pivot to COVID-19 testing:

Diagnostics manufacturers that were able to pivot and fill testing demand – with molecular-, antigen-, and antibody-based COVID-19 tests – are flourishing. Between March and early December, approximately 270 million molecular COVID-19 tests were shipped, including ~200M commercial tests and ~70M extraction reagents.[85] According to AdvaMed's COVID-19 Dx registry, 90-95 percent of COVID PCR and serology testing was manufactured by a small group of companies, including Becton Dickinson, BioMerieux, Bio-Rad Laboratories, Danaher (encompassing Beckman Coulter and Cepheid), Hologic, Ortho Clinical Diagnostics, Roche, Sekisui Diagnostics, Siemens Healthineers, and Thermo Fisher Scientific, among others.[86]

Hundreds of other companies have introduced COVID-19 test offerings, with new innovations rapidly emerging to allow more patients to get tested in whatever way is most convenient for them, including direct-to-consumer methods. Options now include at-home COVID-19 tests, several of which were authorized by the FDA in November and December of 2020.[87]

Although point-of-care and direct-to-consumer testing are not new trends in diagnostics and have struggled in the past due to higher costs and access challenges, COVID-19 has forced their uptake, and the subsector is responding. Indeed, diagnostics manufacturers that have not already added point-of-care to their offerings are now looking at options to expand to meet this new normal, which is not likely to abate in the near term.[88]

Increase in deals, shift in structures:

Due in part to the demand for COVID-19 products and the influx of cash into the subsector, the volume of announced or closed acquisitions of diagnostics manufacturers picked up in 2020, with 46 deals through the first week of November 2020, which represents twice the volume of deals in 2019 and a 45 percent increase over 2018.[89] According to our survey, 63 percent of diagnostic-manufacturer respondents said that the revenues they have realized from COVID-19 testing has allowed them to make more deals in 2020. And looking forward to 2021, 90 percent of our survey respondents say that they expect the number of deals in the subsector to increase (Exhibit 12).

Exhibit 12. Diagnostics manufacturers plan to use influx of cash to increase acquisitions

Source: 2021 healthcare and life sciences investment outlook, KPMG.

[85] Life Science Tools & Diagnostics: COVID-19 Update, JP Morgan, December 2020.

[86] AdvaMed unveils national testing registry to aid in fight against COVID-19, releases first data set, AdvaMed press release, July 21, 2020.

[87] At-home testing, CDC, January 7, 2021.

[88] KPMG diagnostics research, December 2020.

[89] Refinitiv data.

However, while transaction volume increased, deal structures shifted, with acquirers offering larger earnouts to reduce upfront cash and/or equity payments. In transactions where the data was reported, the ratio of potential deal value to upfront cash/equity averaged 1.4x in 2020. That compares with 1.2x for 2019, and 1.3x for 2018.[90] The use of larger earnouts has led to increased potential deal values, which reached approximately 2.3 billion in 2020, a 168 percent increase over 2019, and a 377 percent increase over 2018.[91] In 2021, we do expect some deals to be full consolidations. However, according to survey respondents it is more likely that deals will take the form of strategic partnerships (48 percent) and small strategic tuck-ins (31 percent).

The historic focus on deals involving molecular diagnostic and genetic testing, as well as drug discovery tools, has intensified this year.

- Notable molecular diagnostic and genetic testing deals included: (1) the ~$2.15 billion acquisition of liquid biopsy test kit manufacturer Thrive Earlier Detection by clinical reference lab Exact Sciences[92] and (2) the $1.4 billion acquisition of cancer test kit manufacturer ArcherDx by clinical reference lab Invitae.[93] The valuations of these companies were given a boost by patients' desire for non-invasive testing that can be conducted at home, as well as labs looking to both reference lab and kit options to diversify their offerings. (As previously noted, these two deals are important to the diagnostic labs subsector as well.)
- Notable drug discovery tool deals included: (1) life sciences analytics company Bruker's acquisition of Canopy Biosciences, which specializes in biomarker imaging technologies for cancer,[94] (2) PerkinElmer's $383 million acquisition of Horizon Discovery, a deal designed to bring gene-editing CRISPR technology for therapeutic research and clinical applications to the life sciences company,[95] and (3) gene-sequencing company Illumina's ~$8 billion buy-back of liquid biopsy cancer-screening startup Grail.[96]

Focus on data: Diagnostics now more than just testing

The importance of data has become a major theme in diagnostics over the past years as the volume and complexity of diagnostic patient results have risen. Companies are adding comprehensive biomarker libraries and software compression tools and/or predictive analytics, and technologies that allow synchronization of at-home testing with other tests for disease monitoring. In addition to mergers and acquisitions, labs and diagnostics companies are pursuing strategic partnerships and fundraising around data assets and tools, which will continue to fuel this rise.

Data deals have included Illumina's acquisition of BlueBee to support next-generation sequencing (NGS), as well as a multitude of partnerships, e.g., Labcorp's partnership with data technology company and diagnostic lab Tempus to accelerate clinical trial participation via Tempus's TIME Trial Program, which uses real-time clinical and molecular data to screen and match patients to biomarker-targeted trials.[97, 98] Further, BMS invested $50 million in an upfront payment to launch a neurodegeneration alliance with insitro, a player in the machine-learning world. (The deal involves payment to insitro of an additional $20 million in near-term operational milestones and up to $2 billion in discovery, development, regulatory and commercial milestones).[99] And rounding out this category was the 2020 venture capital funding of over $100 million each to Tempus, ConcertAI, and Verona Health to support their data assets.[100,101,102] We expect the rising data trend across both life sciences and healthcare to continue in 2021 and beyond.

The latter will help Illumina expand its offerings beyond sequencing technology and increase the company's focus on cancer-screening, diagnostics, and cancer-monitoring products.

[90] Informa Pharma Intelligence, November 2020.

[91] Deanna Kamiensi and Maureen Riordan, Dealmaking: Q3 roundup shows deal values jump from prior quarter, Informa Pharma Intelligence, October 27, 2020.

[92] Amirah Al Idris, Exact Sciences snaps up liquid biopsy company Thrive in $2.15B deal, *Fierce Biotech*, October 27, 2020.

[93] Jensen Werley, Invitae completes its $1.4B acquisition of Boulder-based ArcherDX, *BizJournals*, October 5, 2020.

[94] Sean Whooley, Bruker acquires Canopy Biosciences, *Mass Device*, September 11, 2020.

[95] Conor Hale, PerkinElmer snaps up CRISPR provider Horizon Discovery in $383M deal, *Fierce Biotech*, November 2, 2020.

[96] Christina Farr, Illumina buys Jeff Bezos-backed cancer-testing firm Grail in deal worth $8 billion, *CNBC*, September 21, 2020.

[97] Illumina acquires BlueBee to accelerate processing, analysis and sharing of next generation sequencing data at scale, Illumina press release, June 17, 2020.

[98] Tempus and LabCorp announce collaboration to accelerate clinical trial patient participation, Businesswire, September 16, 2020.

[99] Insitro Announces Five-Year Discovery Collaboration with Bristol Myers Squibb to Discover and Develop Novel Treatments for Amyotrophic Lateral Sclerosis and Frontotemporal Dementia, Businesswire, October 28, 2020.

[100] Concerto HealthAI raises $150 Million in Series B funding, Concerto HealthAI press release, January 13, 2020.

[101] Emma Court, Google arm, Bain lead $100 million infusion for health-data startup, Bloomberg, February 5, 2020.

[102] Mary Ann Azevedo, Chicago-Based Tempus Raises $100M At $5B Valuation For AI-Driven Healthcare, Crunchbase, March 16, 2020.

Outlook and investment considerations for 2021

Balancing the need for COVID-19 and non-COVID-19 testing:

Although the need for molecular PCR tests will likely fall once vaccines are fully disseminated, diagnostics manufacturers have found a lasting addition to their portfolios in COVID-19 testing. It is expected to take years for vaccines to be distributed worldwide and, in the meantime, there will still be demand for COVID-19 molecular and antigen testing kits and solutions.[103] Additionally, vaccine clinical trials and post-vaccine tracking of patients' antibody titer levels will continue to drive the need for serology antibody tests.

At the same time, diagnostics manufacturers must continue providing testing for diagnoses in every other therapeutic area. And, there will be more demand for convenient solutions, such as liquid biopsy. Analysts estimate that the market for liquid biopsies in the U.S. alone is in the range of $30 billion to $130 billion.[104] These solutions and others will drive sustained growth in new and classic categories in diagnostics.

Deal trends:

The trend toward more deals related to molecular diagnostic and genetic testing in 2021 is likely to continue and perhaps accelerate. In fact, survey respondents said that the top three areas for M&A activity in the subsector in 2021 are likely to be: (1) point-of-care testing, driven by the pandemic; (2) liquid biopsy, driven primarily by manufacturers desire to have a robust pipeline in key therapeutic areas (e.g., oncology), and (3) next-generation sequencing (NGS), driven equally by enhancing the pipeline and a continuing push for innovation. Of the three, the liquid biopsy segment is expected to have the largest increase in valuation, according to 90 percent of survey respondents.

Investors find these assets particularly attractive because they provide a platform, rather than a one-dimensional product. These platforms enable a more seamless expansion into adjacent indications and give management teams more options for driving growth. Drug discovery assets also have opportunities to move downstream with their biopharma customers to applications in the clinical setting, fueling additional value in biopharma services deals (see the Biopharma Services and Diagnostic Labs section of this report).

Finally, diagnostics manufacturers that moved into COVID-19 testing now have more financial flexibility, which allows them to be more patient with new acquisitions. Instead of looking for an immediate payoff, some companies are now willing to give acquisitions several years to show value for innovations still in development.[105] This trend is supported by our survey, in which 26 percent of respondents said that moving into COVID-19 testing has increased their revenues and allowed them to make non-accretive deals.

The take-away

We expect investment in the diagnostics-manufacturer subsector to center on a couple of major themes in 2021: platform-based assets that have clear applicability to adjacent indications and partnerships or acquisitions that enhance data and analytics capabilities. Diagnostics players will increasingly evaluate assets based on whether they are pursuing partnerships or acquisitions that can expand data and analytics capabilities. Another trend: companies will be reviewing their portfolios for products that could transition to home testing.

Diagnostics manufacturers, always the steady mainstay of the life sciences industry, will be in the spotlight for investors in 2021.

[103] Life Science Tools & Diagnostics: COVID-19 Update, JP Morgan, November 2020.

[104] Christina Farr, Illumina buys Jeff Bezos-backed cancer-testing firm Grail in deal worth $8 billion, CNBC, September 21, 2020.

[105] KPMG diagnostics research, December 2020.

Fairly resilient to change, but with potential for business transformation

Specialty Physician Practices

Specialty physician practices continue to be attractive targets for healthcare investors. These practices achieve value when physician management companies improve financial performance by upgrading front- and back-office functions, using data analytics to understand and manage patient flow, and, more frequently since the pandemic, utilizing virtual health and telehealth capabilities to expand access and meet patient expectations.

Investments are critical for success in this subsector because they fund infrastructure improvements such as innovative models of care and allow the creation of larger and more diverse provider networks through geographical expansion and/or acquisitions of similar or adjacent specialties, leading to better rates in payer negotiations.[106]

How specialty practices fared in 2020

Acquisition drivers:

Specialty physician practices faced challenges in 2020 due to COVID-19. Even so, there was significant deal activity with 208 deals (under the category "physician practices and services") announced and closed in 2020, with 71 deals in Q4-20.[107] During COVID-19 surges patients were less likely to visit surgical or procedural specialists than to visit their primary care physicians.[108] There were widespread cancellations of elective medical visits and surgical procedures (as well as related ancillary/downstream services) that are the bread and butter of many specialist practices. This volume reduction created financial pressures for almost all specialty physician practices, although practices with higher-acuity patients generally fared better financially.

As a result, in 2021 many specialty practices are looking to partner or sell so they can reduce operating costs, attract capital for investment, and potentially bring physician compensation back to pre-pandemic levels. (Many physicians who were furloughed or had diminished schedules during the first months of the pandemic faced significant reductions in compensation due to lower patient volumes or across-the-board pay cuts.[109]) Further, COVID-19 provided an opportunity for health systems to re-evaluate their alignment strategy for hospital-based physicians, with clear evidence of market share increasing for hospital-employed physicians and professional service agreements (PSAs) with physicians owned by private equity at the expense of PSAs with independent physician practices.

As in other areas, specialty physicians turned increasingly to telehealth in 2020. This mode of care had historically been less prevalent in specialty care than in primary care as specialty practices typically require higher-touch interactions with patients. During the pandemic, however, specialists used telehealth technologies to meet consumer expectations for real-time communication and to offer safer alternatives to in-person care. The pandemic also brought regulatory changes that allowed reimbursement for a wider range of virtual services.

Outlook and investment considerations for 2021

Assets in the specialty physician practices subsector continue to be attractive for investment. Key priorities cited by many of our survey respondents included acquiring providers and clinical practices to roll up into expanded provider networks and services in current and/or new markets, as well as acquiring new capabilities like telehealth. One significant challenge that could limit growth and/or investment in this subsector is reimbursement pressure, according to survey respondents.

[106] Evolving physician-practice ownership models, American Hospital Association, 2020.

[107] Sara Hansard, Covid-19 Surges, Vaccines Drive Pharma, Device Deal Growth, Bloomberg Law, December 24, 2020; adapted to include December 2020 data.

[108] Ateev Mehrotra, Michael Chernew, David Linetsky, Hilary Hatch, and David Cutler, The Impact of the COVID-19 pandemic on outpatient visits: A rebound emerges, The Commonwealth Fund, May 19, 2020.

[109] Chris Ober, Peter Lyster, and Brian Hackman, COVID-19 impact on physician compensation, KPMG, June 15, 2020.

Qualities of leading specialty physician practices

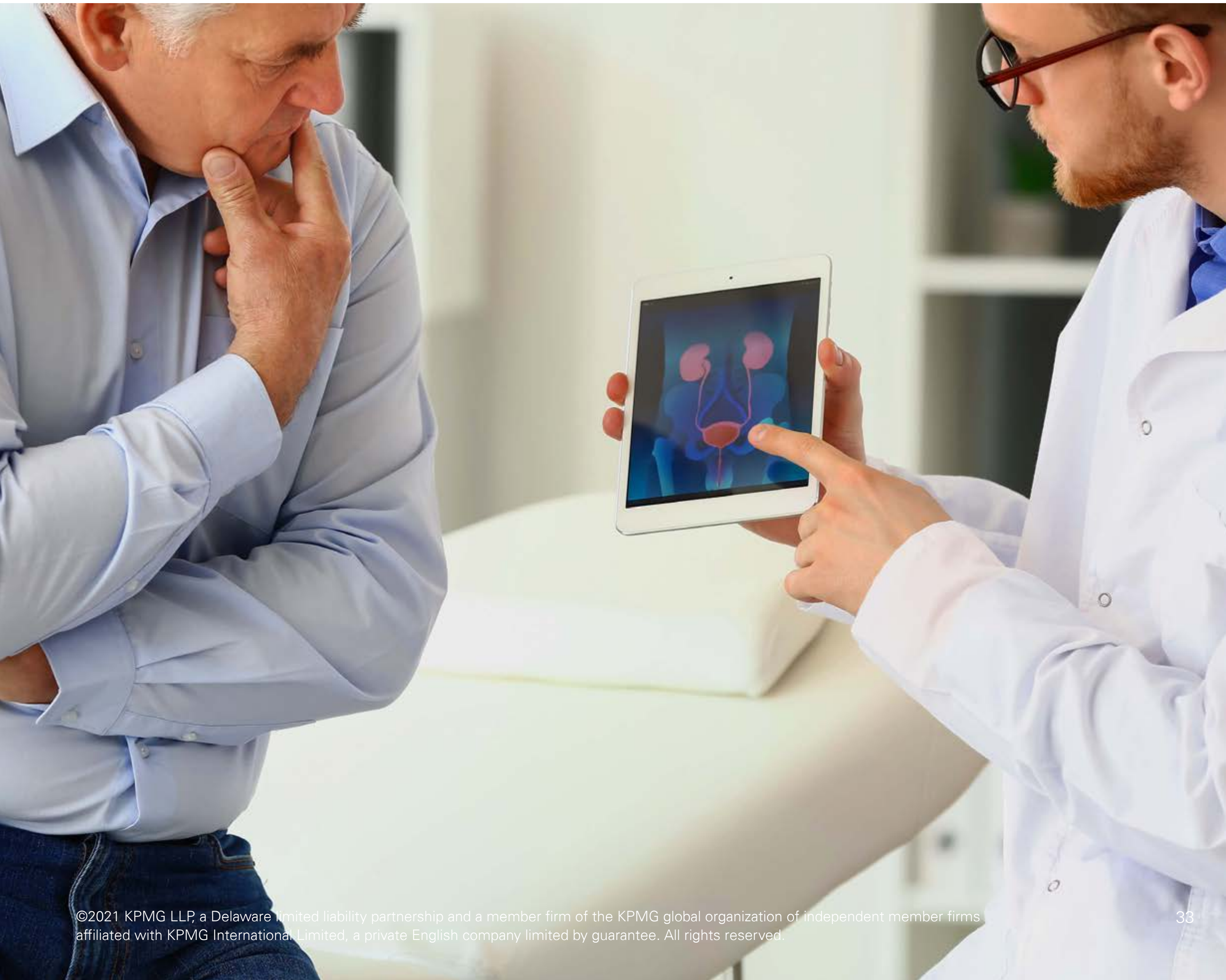
Investors often consider the following when evaluating investment targets in this subsector:

- Whether the practice is risk-bearing or non-risk-bearing and how that impacts compensation models and staffing
- Sufficient capacity in the local market for white space growth through acquisition
- An existing data infrastructure and roadmap to introduce advanced technologies like AI and robotics to expand patient offerings
- A diversified service mix, i.e., whether the practice offers complementary specialties and ancillary services like lab testing, imaging, infusions, and the sale of branded/non-branded retail products

A range of maturity among roll-ups:

Roll-ups have long been under way in specialties that are more likely to involve elective procedures, such as dental, dermatology, ophthalmology, radiology, and physical therapy. Now, investors are starting to focus on specialties that treat patients with chronic conditions, such as gastroenterology and urology. Based on trends in the way healthcare is delivered and the number of deals in the past two years, we expect to see an increase in deals in these specialties in 2021.

There are growing investment opportunities among nephrology, podiatry, orthopedics, and cardiology practices. In addition, an increasing number of procedures are now deemed safe to perform in ambulatory surgery centers (ASCs), a trend that contributes to increases in both physician revenues and PE investment interest. We are seeing ASC companies expand their ownership interests in specialty physician practices that can perform significant volumes of procedures outside of a hospital (e.g., gastroenterology, cardiology, orthopedics, and urology).



Telemedicine as an emerging opportunity:

Consumer interest in remote medical services greatly accelerated during COVID-19 and we expect this will lead to more permanent adoption. Although some specialty appointments and most procedures will require in-person interactions, there are many aspects of specialty care that can be performed remotely. For example, patients can use online platforms to schedule appointments, discuss test results with physicians, receive medication refills or adjustments, ensure proper adherence to recommended self-care protocols, and communicate with their care teams. Although telehealth has potential in all specialties, investments today are particularly prevalent in radiology, pathology, cardiology, and dermatology.[110]

Evolving physician compensation expectations:

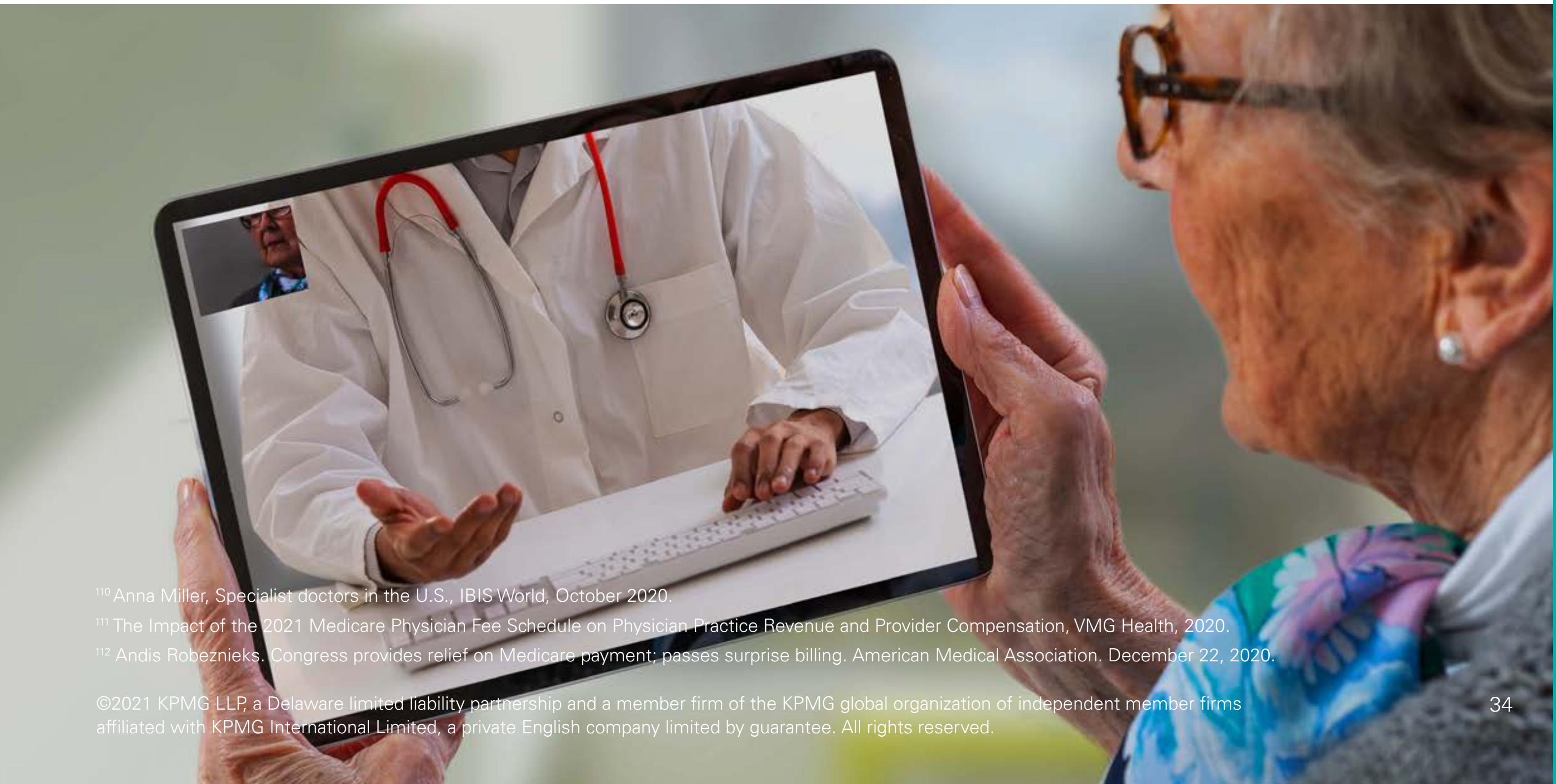
How physicians are compensated will continue to be a key factor for deals in this subsector. Until recently, we have typically seen three compensation models: a fixed salary with no connection to productivity; a full productivity model where compensation is completely tied to work relative value units (wRVUs) or some other productivity measure; and most often, a hybrid model with base pay plus variable pay tied to productivity and, increasingly, quality.

Recently, other compensation models have started to emerge. First, where health systems are moving lower-acuity care to ASCs to improve profitability and prepare for reimbursement changes, physicians can receive incremental wRVUs for performing cases in ASCs rather than in the hospital. In another emerging trend, when an entity acquires the physical assets of a practice and takes a percentage of revenue to provide management/MSO services, part of the proceeds are paid to the physician owners over a period of several years, which effectively boosts compensation while the practice continues to operate independently.

The impact on patient volume from COVID-19 will likely influence which compensation models remain popular or are adopted. Also, the 2021 CMS Physician Fee Schedule Final Rule aims to reform how healthcare costs are valued, reimbursement rates are calculated, and, ultimately, how physicians are compensated.[111] However, the omnibus appropriations bill passed by Congress in late December largely mitigates these impacts by delaying implementation of the evaluation and management (E/M) changes by three years and infusing $3 billion in funding to offset other anticipated reimbursement cuts.[112]

The take-away

Specialty physician practices remain an attractive area of investment, but with some variability across types of specialties and the setting in which services are provided. Investors should consider the current and planned roll-up activity of a given practice to gauge opportunities for future growth and/or diversification.



[110] Anna Miller, Specialist doctors in the U.S., IBIS World, October 2020.

[111] The Impact of the 2021 Medicare Physician Fee Schedule on Physician Practice Revenue and Provider Compensation, VMG Health, 2020.

[112] Andis Robeznieks. Congress provides relief on Medicare payment; passes surprise billing. American Medical Association. December 22, 2020.

Fairly resilient to change, but with potential for business transformation

Home care and hospice

For years, the home care and hospice subsector has been adapting to site-of-care shifts and trends such as the changing landscape for skilled nursing facilities. In 2020, we believe the pandemic likely accelerated a more permanent shift toward patients receiving care in the home. Meanwhile, we expect consolidation to continue, as there are still more than 34,000 home care and hospice providers nationwide, ranging from local "mom and pop" operations to 50 large companies that account for nearly 30 percent of subsector revenue.[113] Attractive targets continue to be those that provide a spectrum of services including:

- Non-medical home care for activities of daily living (ADLs)
- Hospice care in the home
- Home healthcare for the transitional period after a hospital or rehab stay
- High-acuity home health treatments for the chronically ill, which increasingly involve specialized care for certain disease states
- Monitoring of chronically ill patients via telehealth and other electronic means

How they fared in 2020

PDGM growing pains:

Home care and hospice revenue grew at an annualized rate of 2.2 percent to $96.9 billion from 2015 to 2020.[114] This was driven by the trend of shifting elder care to the home and other lower-cost settings and a growing desire by patients to remain in their homes for longer-term care. Although valuations remain high – and despite headwinds from the pandemic and the implementation of patient-driven groupings models (PDGM) – deal volumes increased 17 percent from 76 deals closed or announced in 2019 up to 89 in 2020, including 35 in Q4-20.[115] The CARES Act and Paycheck Protection Program acted as temporary life preservers to the subsector in 2020. And a second tranche of $20 billion from the Provider Relief Fund became available even to home care agencies that began operating in 2020, with applications made available in November 2020.[116] However, volume loss will likely add additional pressure for acquisitions of some home-care operators.

Due to case-volume reductions, total aggregate home health payments from CMS were 21.6 percent lower than projected in 2020.[117] PDGM, which went into effect on January 1, 2020, was designed to reimburse home health providers based on patient characteristics and clinical severity, rather than volume of services.[118] A 4.35 percent "behavioral adjustment" was built into the model, on the assumption that providers would adjust their documentation and coding practices to reflect patients' functional limitations and comorbidities. However, it remains to be seen whether the behavioral adjustment was enough of a buffer to make up for a new method of coding.

[113] Dmitri Diment, Home Care Providers in the US: In good hands: Operators are expected to focus on chronic disease management to spur demand, IBIS World, October 2020.

[114] Ibid.

[115] Sara Hansard, Covid-19 Surges, Vaccines Drive Pharma, Device Deal Growth, Bloomberg Law, December 24, 2020; adapted to include December 2020 data.

[116] Andrew Donlan, HHS adds $20B to provider relief fund for home health agencies, others, Home Health News, October 1, 2020.

[117] Robert Holly, Spending on home health care down 21.6% under PDGM, Home Health News, August 30, 2020.

[118] Home Health Patient-Driven Groupings Model, CMS.

Outlook and investment considerations for 2021

Despite challenges noted above, as well as difficulties with identifying and retaining qualified staff, the home care and hospice subsector has strong fundamentals. The shift to care at home due to continuing avoidance of crowded acute care facilities should be a tailwind for the subsector in 2021 and beyond. Revenues are forecast to increase at an annualized rate of 5 percent to $123.4 billion over the five years to 2025.[119] Since many home care patients are Medicare members, volumes will only continue to grow; however with Medicare Advantage growing as a percentage of total Medicare, reimbursement may be negatively affected. And, although there were some early growing pains, new payment models like PDGM are expected to lead to more deal volume as smaller entities seek to be acquired by larger organizations that can help them deal with compliance complexities related to the new reimbursement model.

Qualities of leading home care and hospice companies

As investors look at potential assets in the home care and hospice subsector, they can:

- Evaluate quality metrics and how the entity has fared since the PDGM model went into effect
- Assess the company's cost structure and recent changes within the cost structure, e.g., resources assigned to cases; RN to LPN mix; licensed PTs vs. OTAs and PTAs, etc.
- Look for companies with strong growth prospects among tens of thousands of enterprises
- Consider whether a company has existing preferred relationships with hospitals, payers, and other referral sources

Chronic disease management:

The aging of the population will continue to drive the prevalence of chronic diseases; the number of older adults will double between 2020 and 2030, according to the CDC.[120] Indeed, in some projections, there could be nearly 171 million Americans with chronic diseases by 2030.[121] To better meet the needs and expectations of the growing senior population across the country, as well as to better control healthcare costs, home care operators are starting to focus more on chronic disease care and chronic disease management. Conditions that require long-term treatment include chronic obstructive pulmonary disease (COPD), hypertension, arthritis, heart disease, chronic kidney disease, and diabetes. Management of these conditions requires coordinated healthcare interventions and communications to support self-care for patients who desire to remain at home. Interventional services include medical and psychological assessments, wound care and pain management, disease and medication management, and education.[122]

Some home care and hospice companies have taken the focus on chronic disease management a step further by creating programs that focus on specialized niche markets. For example, Gentiva Health Services, which was acquired by Kindred Healthcare in 2015, has introduced more than 400 specialty programs, including Gentiva Orthopedics, Gentiva Safe Strides, and Gentiva Cardiopulmonary. Gentiva now generates more than 40 percent of its revenue from these specialty programs,[123] and other agencies are following suit. As this type of service continues to grow over the coming years, home care agencies will be better able to compete with institutional care providers, such as hospitals.

[119] Dmitri Diment, Home Care Providers in the US: In good hands: Operators are expected to focus on chronic disease management to spur demand, IBIS World, October 2020.

[120] Future health of our nation infographic, CDC.

[121] The growing crisis of chronic disease in the United States.

[122] Dmitri Diment, Home Care Providers in the US: In good hands: Operators are expected to focus on chronic disease management to spur demand, IBIS World, October 2020.

[123] Home Health Care Services, Dun & Bradstreet, November 2, 2020.

Partnerships and alliances:

Some home care companies are looking at partnerships and alliances with hospitals and payers as ways to drive growth while improving the patient experience, reducing unnecessary inpatient stays (and related high costs for care), and enhancing quality outcomes across the continuum of care.

Mutual benefits

62 percent of home care survey respondents said they would pursue partnerships with health systems; 38 percent of hospital system respondents said they would pursue partnerships or alliances with post-acute care providers.

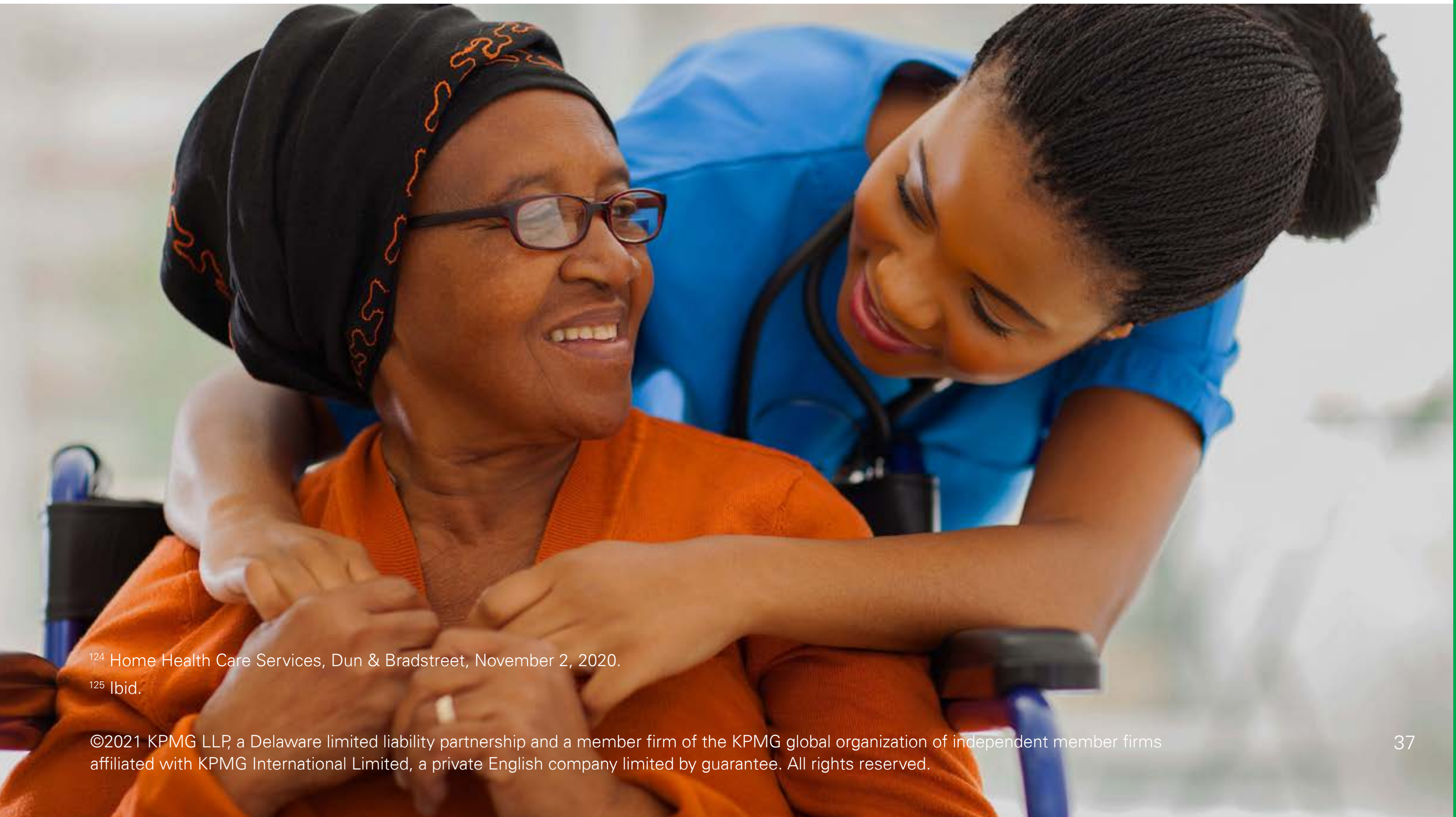
Efforts at partnering across the continuum of care have benefited from ACA provisions that allow home care providers to partner with hospitals, physicians, payers, and others through participation in Medicare bundled-payment pilot programs or Accountable Care Organizations (ACOs).[124] Another Medicare reform measure reimburses home care agencies and hospitals that undertake coordinated efforts to reduce patient readmission rates.[125] In our survey, 47 percent of respondents said they believe that the ongoing movement to alternative payment models (ACOs, Direct Contracting, Primary Care First, specialty-based bundles, etc.) would increase investment in the home care and hospice subsector in 2021.

Technology tools:

The trend toward home care for elderly and chronic-disease patients, which accelerated during COVID-19, is leading a growing number of home care companies to invest in remote health management/monitoring technologies and telehealth services. Remote solutions can also help counter the effects of increasing staff shortages. Applications include telehealth visits, remote monitoring devices, AI chatbots to help alleviate social isolation, virtual nursing assistants to help patients manage chronic conditions while improving engagement and self-management skills, and AI-powered wearables to capture and analyze patient metrics in real time.

The take-away

The home care and hospice subsector is undergoing significant changes in the scope of care they provide and how that care is delivered. Some of these changes have been accelerated by the pandemic. In 2021 and beyond, many organizations in the home care and hospice subsector can expect steady growth, given the increasing population of older Americans with chronic conditions and their desire for home care.



[124] Home Health Care Services, Dun & Bradstreet, November 2, 2020.

[125] Ibid.

Resilience challenged by economic disruption; need to increase innovation and uncover new areas for growth

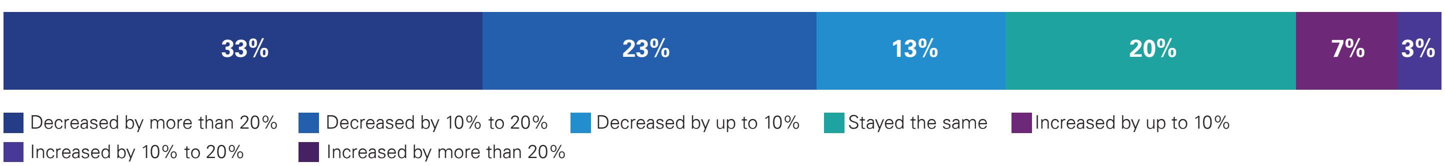
Medical devices

Although the COVID-19 pandemic drove high demand for ventilators and other respiratory devices in 2020, we expect companies in the medical devices subsector to be on a bit of a rollercoaster in 2021. The continuing surge in COVID-19 cases in many geographies across the globe impacts the demand for devices used in elective surgeries. On the other hand, many medical-device companies may be less vulnerable to economic downturns than companies in other subsectors, so demand could quickly rebound to pre-COVID-19 levels as we move beyond the pandemic. Longer term, the aging baby boomer population ensures rising demand for devices, particularly those used in cardiovascular, neurological, and orthopedic treatments.

How they fared in 2020

Medical device manufacturer revenue rose at an annualized rate of 2.7 percent to $47.1 billion from 2015 to 2020,[126] even though revenue fell approximately 4.4 percent in 2020 due to COVID-19.[127] This impacted valuations of device manufacturers that rely on elective procedures: 69 percent of our medical device survey respondents said that they believed valuation of such companies had decreased between 10 percent and 20 percent or more this year (Exhibit 13).

Exhibit 13. Medical device manufacturer valuation decreases in 2020



Source: 2021 healthcare and life sciences investment outlook, KPMG.

Nevertheless, deal-making in medical devices was quite active, with some larger deals that included the following:

- Boston Scientific divested its BTG Specialty Pharmaceuticals business to two affiliates of European specialty pharmaceutical group SERB, in order to focus on their core offering of lifesaving antidotes and ensure that BTG Specialty Pharmaceuticals is part of a fully integrated specialty pharmaceuticals platform.[128]
- After a year of efforts to satisfy antitrust concerns, in November 2020 medical technology leader Stryker finalized its $4 billion acquisition of Wright Medical to further enhance its offering of joint implants.[129]
- Taking advantage of depressed valuations of smaller companies, Medtronic closed seven tuck-in deals in 2020[130] totaling $1.6 billion.[131] These ranged from Medicrea, which makes spine devices that incorporate AI and predictive modeling to create patient-specific implants; to Companion Medical, the privately held manufacturer of the smart insulin pen system InPen; to AI Biomed, which developed the PTeye system to confirm doctors' diagnoses of the presence of parathyroid tissue, among others.[132]

[126] Jack Curran, Medical Device Manufacturing in the US: Life support: Despite an aging population, overall manufacturing performance has hurt revenue, IBIS World, August 2020.

[127] Ibid.

[128] Sean Whooley, Boston Scientific to sell BTG Specialty Pharmaceuticals for $800M, *Mass Device*, December 1, 2020.

[129] Maria Rachal, Stryker closes Wright Medical acquisition after year-long wait, MedTech Dive, November 11, 2020.

[130] Angie Stewart, A timeline of Medtronic's 7 deals so far in 2020, Becker Spine, October 30, 2020.

[131] Medtronic spent $1.6 billion on tuck-in acquisitions in 2020, Modern Healthcare, January 2020.

[132] Angie Stewart, A timeline of Medtronic's 7 deals so far in 2020, Becker Spine, October 30, 2020.

Outlook and investment considerations for 2021

Over the next five years, medical device markets will likely return to normal growth, with revenue expected to increase at an annualized rate of 3 percent to $54.5 billion by 2025.[133] Medical devices and services deal volume was strong toward the end of 2020 with 82 deals in Q4-20.[134] This subsector had 247 announced or closed deals in 2020, which was a 106 percent increase from 2019 and gives the subsector the third highest deal volume for the year, behind biopharmaceuticals and healthcare IT.[135] In 2021, 53 percent of respondents said they expect that small strategic tuck-in deals will be the most popular, followed by 30 percent who expect to see strategic partnerships and 17 percent who anticipate large consolidation deals.

One example of internal growth that will likely be of note to investors: Continuous glucose monitor (CGM) manufacturer Dexcom saw significant growth this year with 2020 revenues expected to be up by ~25 percent to reach around $1.85 billion. As we look forward to 2021 and beyond, the company's growth could be given an additional boost by a five-year collaboration agreement with the University of Virginia to test its CGM technology for use among people with Type 2 and gestational diabetes.[136]

Return of elective surgeries:

Revenue growth -- and investor interest -- will vary widely across medical device segments and depend upon prioritization of elective surgeries.[137] We expect a faster recovery in demand for devices used in less deferrable procedures, e.g., trauma, cardiac surgery, oncology, TAVR, diabetes management, and dialysis. The recovery may take longer for devices used in more deferrable procedures, e.g., hip & knee, ortho extremities, aesthetics, spine surgery, cataract/LASIK, and LAAC. A lot depends on COVID-19: there was a resurgence of procedures requiring major inpatient hospital stays in the second half of 2020, but these fell off again during the recent surge of COVID-19 cases, as did outpatient procedures in specialty physician offices.

More than half of medical-device survey respondents said that they would target elective procedure medical device manufacturers based on the underlying technology, and they are likely motivated by currently depressed prices as well. Therefore, we anticipate significant activity in this subsector in 2021. Further, since ambulatory surgery centers (ASCs) could recover faster than hospitals, device makers whose products are used in those settings may recover more quickly.

The take-away

From a global device perspective, various regions of the world are in different phases of their first or second surge of COVID-19, making pinpointed predictions on return to elective procedures more difficult. Although the medical device subsector will only be watching from the sidelines, the pace of recovery in the subsector is dependent on successful and swift vaccine distribution paired with vigilant testing to keep populations safe and able to undergo surgeries.

[133] Jack Curran, Medical Device Manufacturing in the US: Life support: Despite an aging population, overall manufacturing performance has hurt revenue, IBIS World, August 2020.

[134] Sara Hansard, Covid-19 Surges, Vaccines Drive Pharma, Device Deal Growth, *Bloomberg Law*, December 24, 2020; adapted to include December 2020 data.

[135] Ibid.

[136] Cory Renauer, Dexcom and University of Virginia to advance diabetes research together, Motley Fool, September 24, 2020.

[137] COVID-19: Relaunching elective surgeries – A guide for medical device companies, KPMG, June 2020.

Resilience challenged by economic disruption; need to increase innovation and uncover new areas for growth

Hospitals and health systems

COVID-19 disrupted the entire healthcare industry, but 2020 was particularly challenging for hospitals and health systems. From the first elective surgery suspensions in the spring to the overwhelming surge in virus cases across the country in late 2020, the pandemic has been severely taxing on hospitals from both operational and financial perspectives. Nursing and support staff shortages, provider burnout, and a dramatic decline in non-emergency and elective procedures have strained many hospitals in ways impossible to imagine a year ago. That said, when it comes to the longer-term impact of the pandemic, large, sophisticated health systems are expected to rebound financially, while a growing number of small and rural institutions may not survive on their own.

How they fared in 2020

In the hospital subsector overall, revenue had already been decreasing at an annualized rate of 1.6 percent to $934.8 billion from 2015 to 2020, and, in 2020, the subsector experienced a revenue decline of 18.4 percent.[138] Loss of revenue and high operating expenses are expected to result in full-year operating losses of at least $323.1 billion in 2020, according to a June analysis by the American Hospital Association (AHA),[139] even after accounting for the emergency funding provided under the CARES Act, the Paycheck Protection Program and the Health Care Enhancement Act.

As we moved into the second half of 2020, stronger hospitals, often located in larger metro areas, saw their elective surgery volumes return to near normal levels. However, that progress was interrupted by the year-end COVID-19 surge. Hospitals received CARES Act Provider Relief Funds[140] and rural hospitals received targeted bailout funds through CMS's Community Health Access and Rural Transformation (CHART) model[141] – which helped many institutions stay afloat and deal with the surge. However, the path to financial recovery will be a long one for countless hospitals across the country. A significant number of rural hospitals may not survive without being acquired by less distressed hospitals.

Outlook and investment considerations for 2021

The challenges related to COVID-19, as well as reimbursement pressures and the trend toward providing more services on an outpatient basis, will lead to continued financial challenges for hospitals and health systems, especially ones that just barely survived the initial waves of COVID-19. Many may turn to horizontal consolidation and partnerships, as well as vertical integration. Others will rely on new business models to build scale, gain share of wallet, and access new revenue streams. Across the board, hospitals will explore the possibility of investing in telehealth and other technologies to help them compete with alternative modes of care.

Horizontal consolidation opportunities and obstacles:

Hospital/health system deal volume of closed or announced deals was down 14 percent from 2019 to 2020 but the subsector had a strong Q4-20 with 36 deals.[142] As we look toward a Biden administration, which has already stated its intent to focus on ensuring high-value care, it is likely that there will be increased scrutiny of those hospital deals that could create anti-competitive market power and higher prices, as well as those that are large and cross state lines.[143] In regard to the latter, interstate mergers are more likely to be successful if they entail deal theses

[138] Jack Curran, Hospitals in the US: Apple a day: More patients will likely undergo elective procedures, which is expected to support industry growth, IBIS World, October 2020.

[139] Jacqueline LaPointe, AHA projects $323B in COVID-19 hospital financial losses in 2020, Revcycle Intelligence, July 1, 2020.

[140] CARES Act Provider Relief Fund: Data.

[141] CMS, CHART model.

[142] Sara Hansard, Covid-19 Surges, Vaccines Drive Pharma, Device Deal Growth, Bloomberg Law, December 24, 2020; adapted to include December 2020 data.

[143] Diane Bartz, U.S. needs tougher antitrust enforcement: Biden transition team expert, Reuters, November 12, 2020.

based on expanding best practices, adding digital capabilities, transforming chronic care, and ensuring service-line excellence, as opposed to pursuing scale and better negotiating power with payers and/or streamlining corporate functions and supply chain. It should be noted that any antitrust review is based on a complex rubric that involves service-line market share in hospital service geographies as well as variations in specific market analyses, which may impact the outcome.

Vertical integration:

In 2021, we expect to continue to see vertical integrations that align services across the continuum of care—for example, hospitals forging deals with physician practices, ambulatory surgery centers, urgent care clinics, post-acute care providers, and behavioral health providers. It should be noted, however, that antitrust scrutiny of vertical combinations will likely grow, based upon a likely focus on market concentration by the FTC and the Biden administration.[144]

> "In 2021, nearly half of hospital-industry survey respondents anticipate partnering or aligning with PCP groups or post-acute care providers and investing in providers or tools to help manage medical costs."

Partnerships as an alternative to mergers:

As antitrust scrutiny of hospital mergers continues to increase, partnerships, joint operating agreements, and service-line joint ventures are becoming more common and are expected to increase in 2021.[145] These arrangements are attractive because of lower capital requirements, less regulatory scrutiny, and faster implementation – all of which can lead to value sooner. At the same time, we expect divestitures to continue as some providers shed lower-performing assets and allocate scarce resources to higher-performing ones.

In contrast to full integration achieved via merger, joint operating agreements can provide quick wins in areas like branding and service reconfiguration to optimize profitability. For example, Virginia Mason finalized a joint operating agreement with CHI Franciscan (part of CommonSpirit Health) in January 2021. The deal will build upon existing collaboration between the two legacy organizations, including a radiation oncology center and a joint venture obstetrics unit.[146] Service-line joint ventures allow a more experienced operator with an esteemed brand to add another hospital's service line to garner market share or stem migration away from a specific market. Service-line joint ventures are particularly popular in pediatrics and oncology.

New business models:

Health systems, particularly those with the financial wherewithal and full penetration of existing markets, continue to explore new business models to diversify and access new revenue streams. This includes launching health plans; commercializing capabilities and assets; selling or partnering on the commercialization of retail products in providers' offices or big-box retail stores; expanding the scope of research, general medical education (GME), and associated clinical programming; expanding into cash-pay adjacencies (e.g., senior living, hotels); and forming technology/healthcare innovation partnerships.

Investments in telehealth:

With or without COVID-19, demand will continue to grow for alternative modes of care, including urgent care clinics, retail health, and, of course, telehealth. Telehealth services will likely continue to be an important adjunct to outpatient visits for the remainder of the pandemic and even longer if CMS continues to provide reimbursement for a variety of services that can be provided remotely. At the same time, hospitals are continuing to invest heavily in telehealth capabilities. In fact, healthcare IT and telehealth are the top two areas of investment interest among hospital survey respondents for 2021.

[144] FTC and DOJ issue antitrust guidelines for evaluating vertical mergers, Federal Trade Commission, June 30, 2020.

[145] Sara Hansard, Covid-19 Surges, Vaccines Drive Pharma, Device Deal Growth, Bloomberg Law, December 24, 2020; adapted to include December 2020 data.

[146] Debbie Cockrell, CHI Franciscan, Virginia Mason complete merger, unveil new name for joint health system, The News Tribune, January 5, 2021.

The take-away

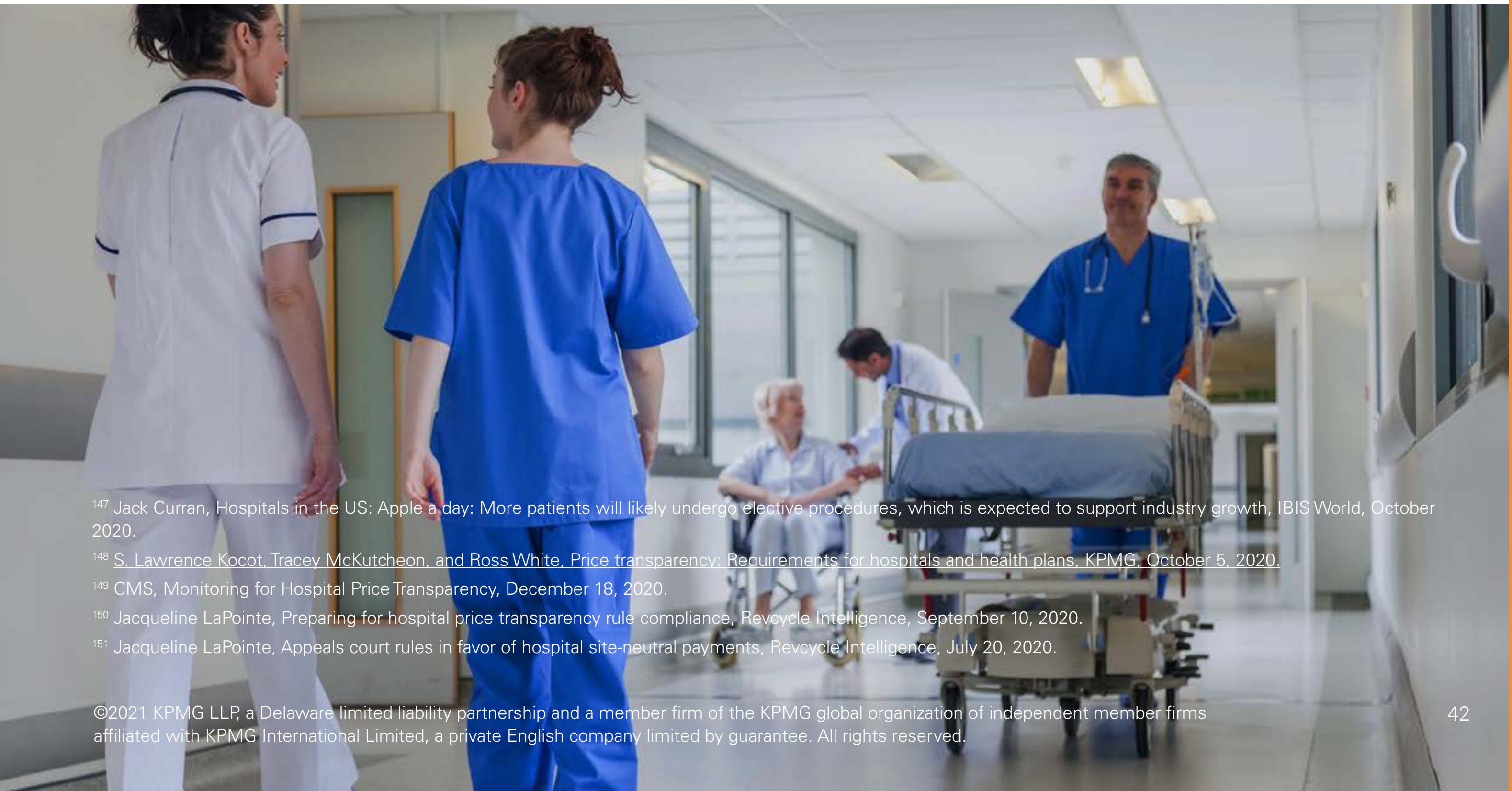
Even as hospitals seek to make up for volume lost during COVID-19 and face continuing competition from alternative service providers, the increasing number of aging patients with Medicare coverage and multiple chronic conditions will likely drive a resurgence of demand for hospital services over the longer term. These factors will support the expected increase in hospital revenue of 2.4 percent annually to reach $1.1 trillion over the five years to 2025.[147]

Regulatory spotlight: Ensuring delivery of high-value hospital care

Hospital operators are keenly aware of the regulatory pressures they may face in 2021. According to our survey, they are most concerned about the impact of value-based-care payment models, interoperability and other healthcare IT mandates, and price transparency requirements.

The Biden administration is likely to continue, and perhaps expand, policies to drive cost and quality transparency and value-based payments tied to clinical outcomes, especially those that originated as part of the Affordable Care Act. CMS's hospital price transparency final rule[148] became effective on January 1, 2020. Providers that don't offer consumer-friendly information about "shoppable services" and "standard charges" can face financial penalties.[149] Although industry groups and hospitals say that disclosing private payer rates would compromise their proprietary contracting agreements and potentially lead to more provider consolidation, a federal judge dismissed their case, paving the way for the rule's implementation.[150]

Finally, hospitals oppose CMS site-neutral payment regulations, which they assert "fail to account for the fundamental differences between hospital outpatient departments and other sites of care." They also argue that implementation could have a negative effect on safety-net hospitals, which are already struggling with funding shortages made worse by COVID-19.[151] However, a U.S. Court of Appeals ruled that the Department of Health and Human Services acted within its statutory authority in implementing hospital site-neutral payments, which will reduce the reimbursement differentials for the same service at different locations, thereby reducing overall healthcare spending.



[147] Jack Curran, Hospitals in the US: Apple a day: More patients will likely undergo elective procedures, which is expected to support industry growth, IBIS World, October 2020.

[148] S. Lawrence Kocot, Tracey McKutcheon, and Ross White, Price transparency: Requirements for hospitals and health plans, KPMG, October 5, 2020.

[149] CMS, Monitoring for Hospital Price Transparency, December 18, 2020.

[150] Jacqueline LaPointe, Preparing for hospital price transparency rule compliance, Revcycle Intelligence, September 10, 2020.

[151] Jacqueline LaPointe, Appeals court rules in favor of hospital site-neutral payments, Revcycle Intelligence, July 20, 2020.

Conclusion

As we look forward to the end of the COVID-19 pandemic and brighter days ahead, the daily counts of new coronavirus cases, hospitalizations and deaths – as well as the economic dislocation and disruption to our lives, families and businesses – will remain seared in our consciousness for many years to come.

Healthcare and life sciences have been at the center of the pandemic response – from hospitals and physician practices providing life-saving patient care, often without PPE, to diagnostic manufacturers innovating to provide accurate testing capabilities, to biopharmaceutical companies developing effective treatments and vaccines in record time. However, this does not mean that the public will expect anything less than high value and higher quality from healthcare providers, or breakthrough innovations from life sciences for diseases and conditions unrelated to COVID-19. In fact, it is likely that the public will demand even more from the healthcare and life sciences industry and subsectors as we move beyond the pandemic and adapt to the new reality that will follow.

While the pandemic has exposed many of the vulnerabilities of the healthcare industry, it has also been an impetus for advancing the connective technologies, interoperability, and commitment to data sharing that will allow the digitalization of the entire healthcare and life sciences ecosystem, as well as the seamless, convenient, and immediate patient experiences healthcare consumers demand. The industry's flexibility, as well as its ability to quickly adapt to a rapidly changing pandemic environment and respond to patients' needs and demands, bodes well for this continued transformation.

Investors have clearly recognized the resilience and innovative thinking of many organizations across the healthcare and life sciences industry as they responded to COVID-19. In many subsectors, 2020 deal-making volumes exceeded initial estimates at the start of last year, despite the pandemic. And at least two subsectors had record years in 2020: Biopharma experienced the most active deal market in history, and the telehealth segment of healthcare IT broke investment records in the first two quarters of 2020.

As our research shows, investment plans – and valuations – for 2021 promise to be robust.

As we look forward to 2021 and beyond, healthcare and life sciences organizations have an opportunity to play a pivotal role in shaping the new reality – even beyond the parameters of their industry and subsectors. The degree to which organizations can continue to evolve and innovate will be key drivers of success, as well as indicators of worthwhile investment opportunities. As healthcare and life sciences investors map out their plans for 2021, our analysis of the ten subsectors covered in this report (see box below) should serve as a catalyst for thinking about where viable opportunities will lie.

Healthcare IT companies, biopharmaceutical manufacturers, and risk-based physician practices *have shown remarkable innovation in their ability to meet the evolving needs of their patients, which has ensured their resilience in the face of economic disruption, as well as growing investment interest and activity.*

Diagnostic labs and diagnostic equipment manufacturers *pivoted in 2020 to provide COVID-related products and services.*

Biopharma services organizations, behavioral health organizations, specialty physician practices, and home care and hospice providers *took the opportunity during the public health crisis to advance several long-awaited structural changes, many of which were facilitated by greater adoption of telehealth technologies. Although finding the strongest assets in these subsectors is a slightly more complex exercise, there are numerous investment opportunities across the spectrum of potential targets.*

Medical device manufacturers and hospitals *were significantly challenged by decreased patient volumes during the pandemic, particularly for elective procedures. Severely taxed assets may not survive without being acquired. At the same time, the aging of the population and the the ability of organizations in these subsectors to find new avenues for growth will likely ensure overall recovery and provide investors with opportunities to target stronger assets that may have temporarily depressed prices.*

How KPMG can help

KPMG LLP is one of the largest providers of professional services – advisory, strategy, audit, and tax – to the healthcare and life sciences industry globally with more than 4,200 industry-specific partners and professionals. The KPMG Healthcare and Life Sciences Strategy practice specializes in advising corporate, private-equity, and public organizations across all phases of the M&A lifecycle from deal strategy to diligence to post-close value creation. Our integrated, multidisciplinary approach provides clients with critical insights into value opportunities—and obstacles to value—at deal speed. The ability to go beyond standard diligence methods will be increasingly important in the post COVID-19 M&A market. Further, KPMG has a proprietary set of tools and methodologies to deliver data-driven insights. Our dedicated healthcare and life sciences M&A teams have extensive experience in mergers, acquisitions, affiliations, JVs, and partnerships across all segments and subsectors of the healthcare and life sciences industry. We understand the regulatory, commercial, operational, and accounting complexities unique to the industry and provide a client-centric, integrated suite of services across the deal lifecycle to assist our clients in achieving business results. For more information about our healthcare and life sciences practice, please visit **https://home.kpmg/us/en/home/industries/healthcare.html.**

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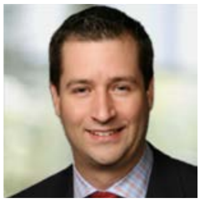

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2021 KPMG Healthcare and Life Sciences Investment Outlook Survey Methodology

KPMG conducted an online survey of healthcare and life sciences investment professionals from November 19, 2020, through December 30, 2020. A total of 286 respondents completed the survey. Survey invitations were sent to business contacts selected by KPMG Deal Advisory & Strategy practice partners and principals, as well as appropriate business professionals identified by Gerson Lehrman Group (GLG), the survey administrator. Respondents were asked to select the primary subsector in which they currently work. They were then asked a series of general questions on the overall industry investment outlook, followed by detailed questions about their selected subsector. Respondents selecting a healthcare subsector were permitted to select up to two additional healthcare subsectors in which to answer questions. Private Equity or Venture Capital respondents were permitted to select up to three subsectors in which to answer questions. As such, each subsector-specific question has a different sample size, varying from 29 to 89. Throughout this paper, any time "survey respondents" are referenced, the 2021 healthcare and life sciences investment outlook survey is the source of the data provided.

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