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The Covid-19 pandemic has triggered immediate and lasting changes to the health-care industry. As the U.S. economy reopens and health-care transactions rekindle, parties to mergers, acquisitions, joint ventures, and affiliations will need to evaluate new legal and business risks related to the pandemic. This article discusses five key topics that organizations should consider when evaluating health-care transactions during and after the Covid-19 crisis.

Participation Risks and Transaction Considerations

Federal and state governments responded to the pandemic by providing unprecedented funding to support health-care operations and the provision of health-care services to patients. The CARES Act and other governmental initiatives included several programs to assist health-care providers and others with expenses and lost revenue associated with the pandemic, including:

- Paycheck Protection Program
- Public Health and Social Services Emergency Fund (PHSSEF, or Provider Relief Fund)
- The Medicare Advance Payments Program and Accelerated Payments Program
- Small Business Administration disaster loans (known as EIDL loans)
- Emergency grant associated with the EIDL loans and the Employee Retention Credit (collectively, the Relief Programs)
- FEMA is also providing assistance to certain institutions

These relief programs are subject to terms and conditions applicable to the receipt and retention of such loans and/or grants. Failure to comply with applicable terms and conditions could result in civil and criminal liability exposure. In many instances, the terms of the relief programs are ambiguous and government guidance regarding their meaning is evolving, thereby increasing the risk of noncompliance and liability exposure. Parties to transactions should evaluate:

- Whether a target organization participated in one or more relief programs and complied with the relevant terms and conditions of the program(s)
- The potential liability of a target related to compliance with the terms and conditions of the relief programs and/or any immediate pre- or post-closing steps that should be taken to mitigate such liability;
- The impact that the transaction could have on eligibility for benefits under the relief programs
- Whether the buyer assumes a seller's compliance obligations under the relief programs post-closing.

Paycheck Protection Program

The Paycheck Protection Program provides federally guaranteed loans to small businesses, including health care organizations, through the Small Business Administration. The loans are attractive to qualifying organizations because they have relatively low interest rates and can be forgiven if the borrower meets certain criteria. The PPP has received considerable media and regulatory attention because of concerns related to the SBA "affiliation rules" which limit eligibility for the PPP if organizations qualify as "affiliates."

From a diligence perspective, potential acquirers should determine whether a target appropriately applied and qualified for the PPP, because the government has made clear that any PPP loan over $2 million will be subject to automatic audit by the SBA. We have already seen government enforcement in connection with the PPP—see here and here. Given the evolving guidance relating to the PPP and the public relations risk for getting it wrong, acquirers should evaluate whether a target that participated in the PPP is likely to withstand an SBA audit and whether the transaction could affect the ability of the target to receive forgiveness of a PPP loan.

Depending on the structure of the transaction, the change in control of the target (or sale of substantially all the assets of the target) could result in an event of default under the PPP promissory note signed with the lender, which could jeopardize the borrower's eligibility for forgiveness. For example, if the bank deems the loan in default and the deal has already closed, then the buyer may have purchased a company that now has more debt than originally anticipated depending on how the PPP loan proceeds were treated during valuation and in the transaction.

As such, in the market, we are seeing sellers and buyers working with the lender/bank and requiring the loan amount to be placed in escrow and released only after forgiveness has been granted. Acquirers should evaluate and discuss with legal counsel, and potentially the lender, whether such loan amount should be placed in escrow until forgiveness has been granted.

HHS Provider Relief Funds

The CARES Act appropriated $100 billion for distribution through the Provider Relief Fund to Medicare and Medicaid providers responding to the Covid-19 pandemic. The Provider Relief Fund is a grant program, as opposed to a loan, and distributions have occurred in several tranches, including a general distribution to Medicare providers, a Medicaid/CHIP targeted distribution for Medicaid and CHIP providers, and other Targeted Distributions to skilled nursing facilities and safety net hospitals, among others. See here for more information. Each of these distributions is subject to different eligibility requirements and application processes.

For instance, on April 10, 2020, known as the first "round" of funding under the General Distribution, the Department of Health and Human Services announced that it would immediately distribute the first $30 billion of a $50 billion "general allocation" to Medicare providers. Notably, there was no application process—the funds were distributed directly to provider accounts based on a methodology adopted by HHS.

On April 22, 2020, known as the second "round" of funding, HHS provided additional guidance on the distribution of the remaining $70 billion of the Provider Relief Fund. The distributions included the remaining $20 billion of the "general allocation," as well as money for specific high-need areas and challenged providers, such as providers serving a disproportionate share of low-income patients—DSH hospitals—and rural providers. HHS extended the deadline for the Medicare Round 2 General Distribution and the Medicaid/CHIP Targeted Distribution to Aug. 28, 2020.

Retention of funds distributed through the Provider Relief Fund Distributions referenced above requires satisfaction of certain eligibility requirements and compliance with terms and conditions through an online attestation. The terms and conditions require that:

- The funds will only be used "to prevent, prepare for, and respond to Covid-19"
- Such funds reimburse the recipient only for health care-related expenses or lost revenues attributable to Covid-19
- The payment will not be used to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse, such as the PPP

Other key terms of the program address balance billing and require that out-of-network providers delivering Covid-19-related care to an insured patient do not collect out-of-pocket expenses from the patient in an amount greater than what the patient would have been required to pay if the care had been provided by an in-network provider. Other general terms incorporate eligibility and documentation requirements regarding compliance with all terms and conditions.

To avoid the government clawing back such funds, health-care organizations should, among other requirements, have processes in place to track spending of the funds on eligible expenses and properly account for lost revenues attributable to the Covid-19 crisis. From a diligence perspective, potential acquirers should determine whether a target has used funds appropriately and has documented such use in a manner consistent with the terms and conditions of the Provider Relief Fund to avoid recoupment of any received funds and other liability exposure. HHS has provided clarifications regarding the use of these funds and other Program requirements in an FAQ document that is updated periodically with HHS guidance.

Medicare Advance Payments and Accelerated Payments Programs

The CARES Act also expanded the provider relief available under the Medicare Advance Payments Program and Accelerated Payments Program. These programs are similar, except for their applicability: Part A providers, including SNFs, submit an "Accelerated Payment" request, while Part B providers—i.e., physicians, suppliers, and DME—submit an "Advanced Payment" request.

The Programs were suspended on April 26, 2020, but providers were able to take advantage of them before that date. From March 28 to April 26, CMS approved more than 21,000 applications totaling $59.6 billion in payments to Part A providers (hospitals) and almost 24,000 applications totaling $40.4 billion in payments to Part B suppliers (physicians, non-physician practitioners, and DME suppliers).

Under the CARES Act, these programs were initially expanded to provide relief to providers and suppliers that lost revenue as a result of restrictions on elective surgery and other procedures, as well as to providers directly treating Covid-19 patients. The programs permit most providers and suppliers to request up to 100% of their Medicare payment amounts for a three-month period. Inpatient acute-care hospitals, children's hospitals, and certain cancer hospitals may request up to 100% of their Medicare payment amount for a six-month period.

The payments are structured as advances on future government program reimbursements, and stipulate a recoupment process where claims submitted by providers/suppliers will be offset from the new claims to repay the accelerated/advance payment. Borrowers have from seven months to one year to repay the advances without interest, depending on their classification.

After such time, the interest rate applicable to the advances jumps to 10.25%. Acquirers should determine whether a target received funds under the programs and whether it intends to repay such funds directly or through recoupment. Congress may extend these repayment deadlines or otherwise change forgiveness requirements as it relates to this program as seen in the Heroes and HEALS Acts, but nothing has been passed as of the date of this publication.

Public-Health Orders, Employee and Patient Safety, and Privacy Considerations

As state economies reopen, health-care organizations must comply with federal, state, and local public health orders. Government agencies, such as the Centers for Disease Control and Prevention (CDC), the Occupational Safety and Health Administration (OSHA), and the U.S. Department of Labor (DOL), have issued Covid-19 guidance related to health-care operations and specific industry segments.

In light of the substantial and evolving guidance related to workplace response to Covid-19, many health-care organizations have established internal planning and response teams to address workplace and patient safety and risk mitigation. Diligence should include review of a target's internal risk assessment and mitigation steps related to Covid-19, including compliance with applicable public-health orders and development of operational procedures for adhering to state mandates and industry guidelines regarding employee and patient safety.

Common controls in the workplace to prevent the spread of Covid-19 should include implementation of the following:

- Preventive measures, e.g., employee temperature checks, face masks and other personal protective equipment
- Social distancing among employees and patients
- Deep cleaning and sanitization of office and patient space
- Re-engineering of waiting rooms and other common areas to ensure distancing between patients
- Spacing of patient visits and scheduling that accounts for enough time to sanitize patient exam rooms between visits
- Employee testing
- Contact tracing
- Privacy policies for employees and patients who either have or have had Covid-19

In addition to assessing a target's proactive risk mitigation steps, diligence should also include a review of applicable liability insurance coverage and relevant state workers' compensation insurance laws to ensure that they extend coverage to employees for Covid-19 infections contracted in the workplace.

Health-Care Regulatory Waivers

In response to the Covid-19 pandemic, the government issued federal and state regulatory waivers temporarily modifying or easing requirements under certain health care laws, including the federal Ethics in Patient Referrals Act (the Stark Law) and the federal Anti-Kickback Statute (AKS). These waivers allow parties to enter into arrangements related to COVID-19 that would otherwise potentially violate the Stark Law or the AKS.

For instance, the Secretary of HHS has issued a partial waiver of the Stark Law for the duration of the Covid-19 public-health emergency. The waiver allows parties to enter into arrangements that do not satisfy certain elements of Stark Law exceptions, including the writing and signature requirements of compensation exceptions, and specific fair market value requirements of the personal services, office lease, equipment lease, and fair market value exceptions. Similarly, the Office of Inspector General announced that OIG will exercise its enforcement discretion and not impose administrative sanctions under AKS for certain remuneration related to Covid-19 that are covered by HHS's Stark Law blanket waivers.

These waivers and exercise of enforcement discretion, however, will automatically terminate upon the conclusion of the federal public-health emergency—or potentially earlier if HHS terminates or narrows them at an earlier date. To the extent that a health-care organization relied on these waivers during the public health emergency, contractual elements implicating the Stark Law or the AKS will need to be re-evaluated when the pandemic ends. Health-care organizations will need to consider termination rights that might be triggered upon the waiver's expiration as well as how reformation of an arrangement to comply with applicable law may impact revenue and operations.

Payor Contracts and Key Business Relationships

Prior to the pandemic, the payor contracts of many providers consisted of traditional fee-for-service contracts. The rapid decline of patient volume for elective and other non-emergent services associated with Covid-19 highlighted a reimbursement vulnerability for providers heavily weighted toward fee-for-service reimbursement arrangements. Health-care organizations will need to consider whether their reimbursement profile can, and should, become more diversified by entering into alternative reimbursement arrangements with payors, including value-based contracts, bundled payments, shared savings, case rates, capitation (such as Medicare Advantage), and episode-of-care payments. Acquirers should evaluate during diligence the organizational readiness of a target entity to implement alternative reimbursement arrangements to mitigate the inherent risk of fee-for-service contracts when patient volume declines.

Similarly, a target's key contractual relationships related to space, staffing, supplies, equipment, financing, and business-critical services have taken on renewed significance in the context of diligence. In particular, acquirers will need to assess whether terms of agreements limit flexibility to terminate, unwind, or enter into alternative arrangements if a target's contractual ecosystem begins to fail.

For example, acquirers should understand whether certain key material supplier arrangements, leases, or other business critical services are terminable without cause upon short notice as these contractual rights and obligations may impact cash flow if the business is required to close down during the pandemic. Acquirers should also evaluate whether, and to what extent, rent or any other deferred payment obligations are due once the public emergency ends and the potential business implications of termination of leased space or key supplier relationships. Weaknesses in business contracting exposed in the Covid-19 context will likely result in strong emphasis on post-closing work plans to course-correct for legal and business issues identified in diligence.

Telehealth Considerations

Covid-19 presented an opportunity to evaluate the effectiveness of widespread adoption of telehealth by providers and consumers. Prior to the pandemic, telehealth services required compliance with a patchwork of complex, state-specific rules and were subject to uncertainty and variability in reimbursement. During the pandemic, state and federal regulators issued waivers of telehealth restrictions in an effort to increase the ability of providers to render care virtually. These waivers relaxed restrictions on provider licensure/eligibility and technology requirements.

Similarly, federal and commercial payors expanded coverage for telehealth services, and CMS is proposing changes to expand telehealth permanently for Medicare beneficiaries consistent with President Donald Trump's Executive Order on Improving Rural and Telehealth Access. Additionally, the Office for Civil Rights (OCR) provided specific guidance regarding relaxation of certain HIPAA privacy and security requirements related to telehealth.

Given the expanded use of telehealth services and the possibility of the pandemic continuing and/or returning, practices should be evaluated for their current telehealth offerings, and their ability to offer services through telehealth in the future since consumers and patients will now expect such offerings.

Key issues to evaluate include:

- Compliance with federal (Centers for Medicare and Medicaid Services) and state waivers, including those regarding equipment requirements/standards and the eligibility of providers to provide telehealth services
- Customer satisfaction and customer ability to use telehealth services
- Payor reimbursement for relevant telehealth services
- The scale of capital investment needed to provide telehealth services through a HIPAA-certified platform—if telehealth services were only performed through federal (OCR) and state-waived technology platforms during the pandemic, this could be a significant investment)

The pandemic ushered in several new legal and business risks associated with health-care transactions. These issues are particularly important because they may impact a target's current and future financial performance long after the pandemic ends. Parties to health-care transactions will need to evaluate these risks as part of diligence and address each party's legal and financial responsibility related to pandemic related risks in the context of the transaction's definitive agreements.