COVID-19 Update: The impact of COVID-19 on health care private equity due diligence

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For private equity transactions going forward during the COVID-19 crisis, and for those occurring several years after it's over, private equity investors will need to perform additional due diligence to evaluate whether and how well targets managed compliance during the pandemic. In particular, investors will need to determine if targets have properly relied on and implemented numerous regulatory waivers and other changes that CMS and other federal and state regulators issued in response to the pandemic. Evaluating compliance with numerous regulatory changes occurring at lightning speed during the pandemic and the transition back to post-COVID 19 requirements will be a high priority for investors evaluating potential targets for private equity investment.

Stark Law blanket waivers

During the crisis, physician practice targets may have entered into amendments to their existing contracts in reliance on the CMS Section 1135 Stark Law blanket waivers. These waivers permit otherwise impermissible financial relationships with physicians during the COVID-19 crisis. Beginning March 1, 2020, and continuing throughout the crisis, the Stark Law blanket waivers allow flexibility by waiving certain requirements that normally must be met to satisfy a Stark exception, such as the personal services or space lease exceptions.

For example, the Stark personal services exception normally requires a hospital to (i) pay compensation that is fair market value (FMV) to a surgery group to provide surgery services to the hospital under a professional services contract and (ii) have a written

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contract or similar writing signed and in place at the start of services. By contrast, the Stark Law blanket waiver permits compensation under a personal services or employment contract to be either above or below FMV, and a writing need not be in place at the start of services, so long as all other requirements of the exception are met.

Similarly, the Stark Law space lease blanket waiver permits a hospital landlord to reduce or suspend rental payments due from a referring physician practice during the pandemic, even though the Stark space lease exception normally requires rent to be FMV.

Another useful blanket waiver allows group practices to furnish certain in-office services, such as imaging services, in locations that do not qualify as a "same building" or "centralized building" under the relevant Stark exception.

The Stark blanket waivers are not a free pass on all of the usual Stark exception requirements, however. They can only be used if they are for one of the specified COVID-19 purposes, and most of the usual requirements of the Stark exceptions still apply. In particular, arrangements still must be commercially reasonable, payments cannot be based on the volume or value of referrals and compensation must be "set in advance". Importantly, the waivers cannot be relied on if the arrangement is found to involve fraud and abuse. Parties must also maintain documentation to be available upon the request of the Secretary of the Department of Health and Human Services (HHS). Undoubtedly, some physician practices will misapply these waivers during the emergency or may fail to maintain adequate documentation.

In the aftermath of the crisis, a key due diligence compliance check will be how well physician practices and other parties relying on the Stark blanket waivers transition back to the post-COVID-19 world. The Stark blanket waivers can only be used during the COVID-19 public health emergency and cannot be relied on after HHS announces that the emergency is over. That means that parties relying on these waivers must plan for the end or transition of arrangements back to full compliance with the usual Stark Law requirements as soon as the emergency ends. Post-pandemic these arrangements will need to either end or comply with a Stark exception.

Physician practices and parties with which they contract will undoubtedly face challenges in managing these changes. Some may fail to smoothly transition back to post-pandemic compliant arrangements in a timely fashion and may end up continuing terms permitted by a blanket waiver that no longer comply with Stark. If they manage the transition poorly, they will have created Stark Law violations resulting in tainted referrals and Medicare overpayments that will need to be evaluated by experienced health care counsel as part of an investor or acquirer's due diligence of targets.

Telehealth Services

Both the Medicare and Ohio Medicaid programs have greatly expanded providers' ability to furnish and bill for telehealth services during the pandemic. In addition to the flexibility afforded under the expanded Medicare and Ohio Medicaid telehealth rules, the HHS Office of the Inspector General (OIG) issued a policy statement that authorizes physicians and other practitioners to provide routine waivers of co-payments or other cost-sharing obligations that patients may otherwise incur when receiving telehealth services. Typically, such a waiver would implicate the federal Anti-Kickback Statute, which prohibits the offering or soliciting of remuneration in exchange for federal health care program business, and the Civil Monetary Penalties Law, which prohibits furnishing inducements to federal health care program beneficiaries. Under the policy statement, the OIG indicates that, so long as a public health emergency is in effect, providers may waive a patient's cost-sharing obligation for telehealth services furnished in accordance with then-applicable coverage and payment rules.

Providers that take advantage of the flexibility afforded by expanded coverage and payment rules, but do not make efforts to return to compliance with the normal rules once the public health emergency is declared over, will be subject to several billing and regulatory compliance issues that will need to be vetted by experienced health care counsel as part of an acquirer's due diligence of acquisition targets that furnish telehealth services.

These and a number of other regulatory changes occurring during the COVID-19 emergency will present significant compliance challenges for physician practices and others who may be targets for private equity investment or acquisition. Physician practices or other transaction targets that do not manage compliance well during the COVID-19 emergency and in the transaction back to

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post-COVID 19 requirements will likely be less attractive transaction candidates for private equity investors, both during the crisis and afterward, due to additional compliance problems.

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