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Hospitals Modify Some Arrangements Without Stark Waiver; Exceptions Are 'Preferable'

By Nina Youngstrom

Some hospitals are giving free or discounted telehealth equipment to physician practices to promote telehealth visits with patients, protected by the blanket waivers of the Stark Law during the COVID-19 public health emergency.[1] While telehealth equipment is a good candidate for the waivers, hospitals might want to anticipate the aftermath, when the public health emergency ends and the waivers expire, because they probably won't be able to provide the equipment at no charge, an attorney said.

"Once the telehealth platform is rolled out, doctors will get used to it," said attorney Victoria Sheridan, with Epstein Becker & Green in Newark, New Jersey, at an Oct. 14 webinar sponsored by the Health Care Compliance Association.[2] When the waivers end, will hospitals offer the equipment to them at fair market value? That option could be written into the arrangement up front to avoid having to reinvent the wheel if hospitals agree to provide the equipment at modified terms after the pandemic. "Think about what your file needs to look like so if I'm using a waiver, I can potentially avoid compliance concerns down the road," Sheridan advised.

Telehealth equipment is one way to capitalize on the blanket waivers of the Stark Law that were announced by HHS Sec. Alex Azar March 30 and are retroactive to March 1. The waivers free hospitals and other entities that provide designated health services from many of the Stark ties that bind them,[3] except indirect financial relationships. But hospitals may be able to skip the waivers and modify or enter into new physician arrangements under existing Stark Law exceptions, which is preferable, she said.

The Stark waivers are available to protect financial relationships that are normally subject to the Stark Law if (1) remuneration and underlying referrals are solely related to COVID-19 and (2) referrals and claims are related to six purposes that were defined in the blanket waiver, Sheridan said. They are:

1. "Diagnosis or medically necessary treatment of COVID-19 for any patient or individual, whether or not the patient or individual is diagnosed with a confirmed case of COVID-19;
2. "Securing the services of physicians and other health care practitioners and professionals to furnish medically necessary patient care services, including services not related to the diagnosis and treatment of COVID-19 … ;
3. "Ensuring the ability of health care providers to address patient and community needs due to the COVID-19 outbreak … ;
4. "Expanding the capacity of health care providers to address patient and community needs due to the COVID-19 outbreak;
5. "Shifting the diagnosis and care of patients to appropriate alternative settings due to the COVID-19 outbreak … ; or

6. "Addressing medical practice or business interruption due to the COVID-19 outbreak."

Hospitals Still Must Satisfy Other Requirements

The waivers aren't an invitation to ignore Stark Law exceptions in their entirety. "What the waivers mean is there might be one or two components of an exception you don't need to satisfy if a COVID-19 purpose is met," Sheridan said. In April 21 explanatory guidance on the waivers,[4] CMS clarified that hospitals must still satisfy nonwaived requirements of an applicable exception. For example, while a waiver might allow hospitals to pay a physician above fair market value compensation in a personal services arrangement, they still have to meet the other requirements of the exception, such as setting compensation in advance.

HHS waived 18 aspects of the Stark Law. Many of them implicate fair market value.[5] "I'm sure you had a reaction similar to mine when the waivers were first published: Wow, this is great. But then, when will we actually use them?" HHS filled in some of the blanks. For example, hospitals are allowed to pay above-market compensation to physicians for performing professional services, particularly in challenging or hazardous environments. They also can go above the $423 per year per physician cap on nonmonetary compensation to provide things like continuing medical education related to COVID-19, supplies, food, isolation-related needs (e.g., hotel rooms and meals), child care or transportation.

But the temptation of the Stark waivers might obscure the fact that perhaps hospitals won't depend on them, Sheridan said. "It's helpful to think about when these waivers can be used, but also important to emphasize a point made by HHS when the waivers were issued: Reliance on the waivers may not be necessary because many financial relationships related to COVID may be able to satisfy the requirements of a Stark Law exception," she said. "If you can satisfy an existing exception, that's preferable." For one thing, a Stark-compliant arrangement will outlast the pandemic. For another, there's "less clarity on how CMS views certain aspects of the waivers," Sheridan said. That's a far cry from the large body of notice and comment rulemaking and advisory opinions on how CMS interprets the Stark regulations, which helps guide hospitals in structuring and reviewing arrangements. That's why they may be better off modifying an arrangement for COVID-19 purposes using an existing Stark exception, "as long as you plan for another change down the road," Sheridan said. "If you have the ability to think ahead, you can probably modify compensation to consider COVID without needing to rely on a waiver."

She recommended bringing the business, compliance and legal teams together when entering into a new or modified arrangement (e.g., personal services, employment) "to make sure everybody's objectives are being met." For example, hospitals that pay physicians based on productivity may be able to prospectively amend their compensation arrangements to adjust the dollar amount paid per work relative value unit (RVU) or the threshold for earning a work RVU bonus because COVID-19 has depressed productivity. Hospitals also might be amending arrangements because they want physicians to provide additional or new administrative services. For example, before the COVID-19 pandemic, hospitals typically had "ongoing but relatively minimal administrative time" devoted to infectious disease specialists, Sheridan said. Now the demand is high clinically and administratively.

Hospitals also should be prepared for enforcement actions from the HHS Office of Inspector General (OIG) and the Department of Justice (DOJ). "Regardless of COVID, there will always be a focus on physician arrangements with referral sources," she said. "Don't think OIG or DOJ will say, 'Everyone is trying to do what's right,' and not look at physician arrangements," although so far COVID-19 fraud enforcement has focused on what would be considered black-and-white fraud.

Appraisers Will Look for New Methodologies

COVID-19 has thrown a wrench in valuations and physician compensation, said Daniel Stech, senior director at the Carnahan Group Inc., in Castle Rock, Colorado, at the webinar. "We will find arrangements that may not be supportable under traditional methods," he said. "Some hospitals will be forced to reduce compensation, but if there's a defensible case to be made, many hospitals will take that risk and continue to support the compensation arrangements." For example, smaller community hospitals may be recruiting critical care specialists whom they normally don't require full time. "The hospital either will have to negotiate with the provider to get them to accept a lower salary to fit within the fair market value range of an appraiser, or they may have to make a judgment that says this is a necessary provider and service, and we understand our appraiser can't support [a higher] level of pay, but we may take that risk in light of the public health emergency," Stech said.

Appraisers probably will develop new methodologies or base valuations on different assumptions. Normally, when evaluating compensation for 2021, appraisers would look at the prior year's work RVUs, professional fee collections and other markers of productivity, he said. But in light of the decrease in office visits and elective surgeries, he doubts appraisers will consider a physician's 2020 performance a good representation. For physicians with a track record, appraisers will look at 2019 performance. For new physicians without a history, appraisers will have to rely on benchmark data or other research for that specialty. In markets with alternative payments models, where physicians are engaged in population health management, Stech predicts the development of compensation based on patient panel sizes—"per-member, per-month-type compensation instead of work RVU compensation."

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1 CMS, "Blanket Waivers of Section 1877(g) of the Social Security Act Due to Declaration of COVID-19 Outbreak in the United States as a National Emergency," March 30, 2020, https://go.cms.gov/2JuPI8a.
2 Gary Herschman, Victoria Sheridan, and Daniel Stech, "Physician Compensation in the Time of COVID: Compliance and Alignment Challenges," webinar, October 14, 2020.
3 Nina Youngstrom, "Blanket Waiver Says Bye to Stark Law for COVID-19 Reasons, Except Indirect Financial Arrangements," *Report on Medicare Compliance* 29, no. 13 (April 6, 2020), https://bit.ly/2XnWODJ.
4 CMS, "Explanatory Guidance: March 30, 2020 Blanket Waivers of Section 1877(g) of the Social Security Act," April 21, 2020, https://go.cms.gov/3f2W0KS.
5 Nina Youngstrom, "Stark Waivers Related to Fair Market Value and Valuation," *Report on Medicare Compliance* 29, no. 37 (October 19, 2020).