CMS Issues Broad Stark Law Waiver for COVID-19

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PROFESSIONAL

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On March 30, 2020, CMS issued a broad waiver of the Stark law, pursuant to its authority under Section 1135 of the Social Security Act, with a retroactive effective date to March 1, 2020. This waiver is critical as providers are facing unprecedented circumstances, and where patient care needs and public health initiatives require significant flexibility with respect to physician financial relationships that the Stark law does not otherwise provide. The blanket waiver contains the following element

- The waiver is ***nationwide, effective March 1, 2020***, and will terminate or be narrowed only on a prospective basis. CMS will pay claims for designated health services that, but for satisfying the conditions of a blanket waiver, would violate the physician self-referral law.
- The parties must make records relating to the waiver available to the Secretary on request (and thus are well advised to create contemporaneous documentation), but they ***need not apply to CMS to use the waiver***.
- Although the waivers apply only for referrals and financial relationships related to COVID-19 purposes, the term "COVID-19 purposes" is defined very broadly to permit a wide array of services and arrangements including securing the services of physicians to furnish medically necessary services in response to the COVID-19 outbreak (even if not related to diagnosis and treatment of COVID-19), and arrangements addressing medical practice or business interruption due to COVID-19 to maintain the availability of medical care and related services for patients and communities.
- The waiver is available to providers who furnish items and services in good faith "but are unable to comply with one or more of the specified requirements … [of the Stark law] as a result of the consequences of the COVID-19 pandemic…." Therefore, if relying on the waiver, an important consideration is whether the particular arrangement is necessary as a consequence of the COVID-19 pandemic, or merely more convenient. As an alternative to relying on the waiver, providers could always look at other options to either re-structure existing agreements or enter into new agreements that satisfy the Stark law and don't require use of the waiver. CMS also notes that it retains enforcement discretion if it makes a determination of fraud and abuse.

The waiver provides several examples of arrangements that otherwise might not comply with the Stark law, but are permitted under the waiver. These include, to

name just a few:

- premium pay for working in hazardous conditions;
- remuneration for items or services that is above or below fair market value;
- rent for space or equipment that is above or below fair market value;
- low interest or interest-free loans to physicians whose revenue has been impacted;
- provision of telehealth equipment to facilitate working remotely;
- provision of meals, comfort items, and childcare for physicians spending long hours at a hospital;
- arrangements that are not documented in a written agreement signed by the parties;
- referrals to a physician-owned hospital that has temporarily expanded its capacity;
- physician-owned ambulatory surgery center that enrolls as a hospital; or
- referrals to a physician-owned home health agency outside of a rural area.

This waiver will be tremendously helpful to the healthcare field as it scrambles to respond to the pandemic. However, it is not unlimited. For example, if a physician tenant is struggling to pay rent to a hospital or other "entity" (as that term is defined under the Stark law), a question could arise as to whether abatement of rent in its entirety, as opposed to deferral or reduction of rent, is the appropriate approach in a particular circumstance in response to COVID-19. Documentation of the determination that the particular arrangement is necessary due to the COVID-19 outbreak would be helpful support if questioned.

In addition, providers should monitor developments closely, since the waiver corresponds directly to the COVID-19 pandemic, and will have an end date. Providers may need to be prepared to resume compliance with the Stark law at that time, as it is currently not clear whether arrangements entered into during this period will be considered grandfathered.

If you have questions about the application of this waiver to any physician financial relationships at your organization, please feel free to contact the lawyer in the firm who handles your matters or one of the lawyers listed below.

HLB's Coronavirus Task Force is monitoring developments closely. For federal and state resources on COVID-19, please refer to our COVID-19 Resource Page.

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For further information, please contact Charles Oppenheim *or* Nina Adatia Marsden *in Los Angeles,* Amy Joseph *in Boston,* Ben Durie *in San Francisco, or your regular Hooper, Lundy & Bookman contact.*

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