

## **Blanket Waiver on Stark Law Sanctions Provides Limited Relief in Light of Pandemic**

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On March 30, 2020, the Secretary of the U.S. Department of Health and Human Services issued a "blanket waiver" impacting the physician self-referral law known as the Stark Law. The blanket waiver—which is retroactively effective to March 1, 2020—waives sanctions under the Stark Law relating to certain financial relationships and referrals that are specifically related to the COVID-19 pandemic and do not otherwise fall within one of the Stark Law exceptions.

The Stark Law generally prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to any entity with which he or she, or an immediate family member, has a financial relationship, unless the requirements of an applicable regulatory exception are met. It further prohibits the entity from billing for DHS that are provided pursuant to a prohibited referral.

Under the blanket waiver, Centers for Medicare & Medicaid Services (CMS) not only waives sanctions under the Stark Law for certain financial relationships and referrals that do not meet the requirements of a regulatory exception, but will also pay claims for DHS that, but for satisfying the conditions of the waiver, would violate the Stark Law. Application of the waiver is contingent on the following conditions being met: (1) the remuneration is directly between the entity and the physician, the physician organization in whose shoes the physician stands, or an immediate family member of the physician, and (2) the remuneration and referrals are solely related to COVID-19 purposes.

What does it mean to be solely related to COVID-19 purposes? The blanket waiver defines this term to mean one of six situations which is generally geared toward the diagnosis or treatment of COVID-19 (whether or not the patient is diagnosed with the disease) and requires ensuring/securing the services of health care providers necessary to address patient and community needs in light of the pandemic.

At the heart of the blanket waiver are 18 enumerated situations in which—absent a determination of fraud or abuse—health care providers may be reimbursed with no sanctions under Stark. These include:

- Payments to a physician that are above or below fair market value (FMV) for services rendered by the physician.
- Rental charges for office space and/or equipment that are below FMV.
- The provision of medical staff incidental benefits that exceed the regulatory limit.
- Remuneration from a physician to an entity that is *below* fair market value for the use of the entity's premises or for items or services purchased by the physician from the entity.

The Secretary provided additional clarity by including 19 specific examples of remuneration, referrals, and conduct that may fall within the scope of the waiver, including:

- A hospital paying physicians above their previously contracted rate for furnishing professional services for COVID-19 patients in particularly hazardous or challenging environments.
- A hospital renting office space or equipment from an independent physician practice at below fair market value or at no charge in order to accommodate patient surge.
- A hospital's employed physicians using the medical office space and supplies of independent physicians to treat patients who are not suspected of exposure to COVID-19 away from their usual medical office space on the campus of the hospital in order to isolate patients suspected of COVID-19 exposure.
- An entity providing free telehealth equipment to a physician practice to facilitate telehealth visits for patients who are observing social distancing or in isolation or quarantine.
- A hospital providing meals, comfort items, or onsite child care with a value greater than \$36 per instance to medical staff physicians who spend long hours at the hospital during the COVID-19 outbreak in the United States.

A full listing of blanket waivers and examples of their application, can be found in the Secretary's Blanket Waiver.

Entities relying on this blanket waiver to maintain compliant financial relationships should regularly check the CMS website for up-to-date information and to monitor any changes that may be issued. In addition, entities are advised to keep detailed records relating to their use and application of the waivers, which records may be requested.