



HEALTH LAW ALERT

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CMS Issues Waiver for Stark Law and COVID-19

On March 30, 2020, the Center for Medicare and Medicaid Services (“CMS”) announced that it had issued a waiver of sanctions under the physician self-referral law (“Stark Law”) retroactive to March 1, 2020, in response to the COVID-19 pandemic. The Stark Law prohibits a physician from making referrals for certain healthcare services payable by Medicare or Medicaid if the physician (or an immediate family member) has a financial relationship with the entity performing the service. The Stark Law does provide for certain statutory and regulatory exceptions. The Stark Law waiver is one of a sweeping set of waivers that CMS issued as part of its COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers. It is intended to provide flexibility to health care providers attempting to respond rapidly and effectively to the COVID-19 outbreak by lowering many administrative hurdles to and other restrictions on effectuating critical financial relationships. Physicians seeking to operate under the Stark Law waiver must be mindful of its limitations. According CMS issued guidance the Stark Law waiver applies to remuneration and referrals that must be solely related to “COVID-19 Purposes” which includes:

- Diagnosis or medically necessary treatment for any patient or individual, whether or not the patient or individual is diagnosed with a confirmed case of COVID-19;
- Securing the services of physicians and other health care practitioners to furnish medically necessary patient care services, including services not related to the diagnosis and treatment of COVID-19;
- Ensuring the ability of health care providers to address patient and community needs due to COVID-19;
- Expanding the capacity of health care providers to address patient and community needs due to COVID-19;
- Shifting the diagnosis and care of patients to appropriate alternative settings due to COVID-19; or
- Addressing medical practice or business interruption due to COVID-19 in order to maintain the availability of medical care and related services for patients and the community.

According to the CMS guidance, remuneration provided for COVID-19 Purposes and is “absent the government’s determination of fraud or abuse” for which CMS will not impose Stark Law sanctions include:

- Hospitals and other health care providers paying above or below fair market value to rent equipment or receive services from physicians or vice versa. For example, a physician practice may be willing to rent or sell needed equipment to a hospital at a price that is below what the practice could charge another party, or a hospital may provide space on hospital grounds at no charge to a physician who is willing to treat patients who seek care at the hospital but are not appropriate for emergency department or inpatient care.



- Health care providers supporting each other financially to ensure continuity of health care operations. For example, a physician owner of a hospital may make a personal loan to the hospital without charging interest at a fair market rate so that the hospital can make payroll or pay its vendors.
- Hospitals providing benefits to their medical staffs. For example, multiple daily meals, laundry service to launder soiled personal clothing, or childcare services while the physicians are at the hospital and engaging in activities that benefit the hospital and its patients.
- Allowing the provision of certain items and services that are solely related to COVID-19 Purposes (as defined in the waivers), even when the provision of the items or services would exceed the annual non-monetary compensation cap. For example, a home health agency may provide continuing medical education to physicians in the community on the latest care protocols for homebound patients with COVID-19, or a hospital may provide isolation shelter or meals to the family of a physician who was exposed to the novel coronavirus while working in the hospital's emergency department.
- Physician-owned hospitals temporarily increasing the number of their licensed beds, operating rooms, and procedure rooms, even though such expansion would otherwise be prohibited under the Stark Law. For example, a physician-owned hospital may temporarily convert observation beds to inpatient beds to accommodate patient surge during the COVID-19 pandemic.
- Loosening some of the restrictions when a group practice can furnish medically necessary designated health services (DHS) in a patient's home. For example, any physician in the group may order medically necessary DHS that is furnished to a patient by a technician or nurse in the patient's home contemporaneously with a physician service that is furnished via telehealth by the physician who ordered the DHS.
- Group Practices. Group practices furnishing medically necessary MRIs, CT scans or clinical laboratory services from locations like mobile vans in parking lots that the group practice rents on a part-time basis.

As the facts of each arrangement are different, it is important that they be carefully reviewed to ensure that the financial relationships and/or referrals are consistent with the Stark Law waiver. Additionally, each arrangement must be reviewed to ensure that it does not run afoul of other applicable federal and state laws including the New York State Ethics in Patient Referral Act, which is New York's version of the federal Stark Law. Finally, while notifying CMS of the Stark Law waiver is not required, those taking advantage of the waiver must make records relating to its use available to CMS upon request.

If you have any questions, please contact
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