

Publications

Health Care Alert: HHS Issues Sweeping Relief for Potential Stark Law Concerns in Battling COVID-19

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On March 30, 2020, the Secretary of the Department of Health and Human Services (the Secretary) issued 18 blanket waivers of sanctions under the physician self-referral law (Stark) to provide vital flexibility for physicians and providers in the fight against COVID-19. The blanket waivers are retroactive to March 1, 2020, nationwide.

Purpose of the Blanket Waivers

The Secretary issued the blanket waivers to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid, and CHIP programs. Importantly, the waivers apply to health care providers who furnish items and services in good faith, but are unable to comply with certain requirements of Stark as a result of the COVID-19 pandemic. For as long as the waivers are in effect, health care providers may seek reimbursement for such items and services and be exempt from otherwise applicable sanctions for noncompliance with Stark, absent the government's determination of fraud or abuse.

Prerequisites to Utilizing Blanket Waivers

The blanket waivers apply only to financial relationships and referrals of items and services that relate directly to addressing the COVID-19 outbreak in the United States. Remuneration must be directly between an entity and: (1) the physician or the physician organization in whose shoes the physician stands under 42 CFR 411.354(c); or (2) the immediate family member of the physician. The remuneration and referrals described in the blanket waivers must be solely related to "COVID-19 Purposes," meaning:

- 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;
- 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, in response to the COVID-19 outbreak;

- Ensuring the ability of health care providers to address patient and community needs due to the COVID-19 outbreak;
- Expanding the capacity of health care providers to address patient and community needs due to the COVID-19 outbreak;
- Shifting the diagnosis and care of patients to appropriate alternative settings due to the COVID-19 outbreak; or
- Addressing medical practice or business interruption due to the COVID-19 outbreak in order to maintain the availability of medical care and related services for patients and the community.

Blanket Waiver Provisions

Provided the above prerequisites are met and, absent a finding of fraud and abuse, the blanket waivers include the following situations:

Fair Market Value Waivers

- Remuneration from an entity to a physician that is above or below the fair market value for services personally performed by the physician to the entity.
- Rental charges paid by an entity to a physician [1] that are below fair market value for the entity's lease of office space from the physician.
- Rental charges paid by an entity to a physician that are below fair market value for the entity's lease of equipment from the physician.
- Remuneration from an entity to a physician that is below fair market value for items or services purchased by the entity from the physician.
- Rental charges paid by a physician to an entity that are below fair market value for the physician's lease of office space from the entity.
- Rental charges paid by a physician to an entity that are below fair market value for the physician's lease of equipment from the entity.
- 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.
- Remuneration from an entity to a physician resulting from a loan to the physician with an interest rate below fair market value or on terms that are unavailable from a lender that is not a recipient of the physician's referrals or business generated by the physician.
- Remuneration from a physician to an entity resulting from a loan to the entity with an interest rate below fair market value or on terms that are unavailable from a lender that is not in a position to generate business for the physician.

Medical Staff and Nonmonetary Compensation Waivers

- Remuneration from a hospital to a physician in the form of medical staff incidental benefits that exceeds the limit set forth in 42 CFR 411.357(m)(5).
- Remuneration from an entity to a physician in the form of nonmonetary compensation that exceeds the limit set forth in 42 CFR 411.357(k)(1).

Miscellaneous Waivers

Additional waivers are available for situations involving: (i) physician-owned hospitals, (ii) physician-owned home health agencies, (iii) referrals in group practices that fail to satisfy certain group practice requirements, (iv) referrals by physicians to entities owned by immediate family members, and (v) compensation arrangements that do not satisfy the writing or signature requirement(s) of an applicable Stark exception.

Each blanket waiver is limited to the circumstances described in the waiver, and health care providers must satisfy all conditions of the applicable waiver. The full details of the blanket waivers are available [here](#).

Record-Keeping Requirement

While the blanket waivers do not require the submission of any documentation or notice to the Secretary or the Centers for Medicare & Medicaid Services (CMS) in advance of their use, parties must document and maintain records of their eligibility for and use of the waivers and make such records available to the Secretary upon request.

Although we have not seen any similar waivers of the Anti-kickback Statute or civil monetary penalties law, CMS has issued a number of blanket waivers offering flexibility for health care providers on a variety of issues, including, among others, Emergency Medical Treatment & Labor Act (EMTALA), medical staff privileging and credentialing, discharge planning, telemedicine, and Quality Assurance and Performance Improvement (QAPI) programs. Providers can access the full details of the various CMS waivers [here](#) or provider-specific fact sheets [here](#).

If you have questions about these waivers and their impact on your organization or business, please contact Jolie Havens, Matt Albers, Suzanne Scrutton, Liam Gruzs, Stephanie Angeloni, or your regular Vorys attorney.

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Vorys COVID-19 Task Force

Vorys attorneys and professionals are counseling our clients in the myriad issues related to the coronavirus (COVID-19) outbreak. We have also established a comprehensive Coronavirus Task Force, which includes attorneys with deep experience in the niche disciplines that we have been and expect to continue receiving questions regarding coronavirus. Learn more and see the latest updates from the task force at vorys.com/coronavirus.

[1] Note that the term “physician” may also include the immediate family member of the physician depending on the specific requirements of the waiver.