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# Stark Law Blanket Waivers Related to "COVID-19 Purposes" Announced

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The COVID-19 pandemic has led to rapid and drastic changes to health care delivery in the United States, including as it relates to arrangements between health care providers and physicians that may implicate the federal physician self-referral law, or "Stark Law." On March 30, 2020, the Centers for Medicare & Medicaid Services ("CMS") issued much-anticipated nationwide blanket waivers of sanctions under the Stark Law for "COVID-19 Purposes" (the "Stark Blanket Waivers"), which are available here. The Stark Blanket Waivers have a retroactive effective date of March 1, 2020 and will continue through the end of the Public Health Emergency ("PHE") that was declared related to the COVID-19 outbreak. The Stark Blanket Waivers, which were issued under Section 1135 of the Social Security Act, permit numerous flexibilities to ensure that: "(1) sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid, and CHIP programs; and (2) health care providers . . . that furnish such items and services in good faith, but are unable to comply with one or more of the specified requirements of [Stark] as a result of the consequences of the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent the government's determination of fraud or abuse." These flexibilities provide welcome relief for health care providers that are facing much uncertainty and overwhelm in this time of rapid and drastic change.


Stark is a strict liability law with very significant civil penalties and prohibitions on billing the Medicare program associated with its violation. However, during the PHE, CMS will reimburse for services provided pursuant to referrals that would otherwise violate Stark, and will not impose penalties, as long as the Stark Blanket Waivers are followed. It is important to keep in mind that each Stark Blanket Waiver is limited to the specific circumstances described in the waiver. Health

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care providers are required to satisfy every condition of the Stark Blanket Waiver in order to take advantage of it, so special attention should be paid to the requirements.

CMS cautioned that any remuneration described in the Stark Blanket Waivers must be directly between the entity and: (1) the physician or the physician organization in whose shoes the physician stands under 42 C.F.R. § 411.354(c); or (2) the immediate family member of the physician. Further, CMS cautioned that the remuneration and referrals described in the Stark Blanket Waivers must be solely related to "COVID-19 Purposes." CMS specifies that "COVID-19 Purposes" means, for purposes of the Stark Blanket Waivers:

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

There are eighteen Stark Blanket Waivers. It is critical to know that each waiver is specific in its requirements and application, so health care providers should not rely on this summary in order to use a Stark Blanket Waiver. Instead, providers should carefully review the details of each waiver prior to making a decision to proceed with an arrangement in reliance on a waiver. A few of the Stark Blanket Waivers are briefly summarized as follows:

- Remuneration to a physician that is above or below fair market value for services personally performed by the physician.
- Rental charges paid to a physician that are below fair market value.
- Remuneration to a physician in the form of medical staff incidental benefits or non-monetary compensation that exceeds the limits set forth in applicable Stark regulations.
- Loans to a physician with below fair market value interest rates or on terms that are not available from a traditional lender.
- Referrals by a physician owner of a hospital that temporarily expands its facility capacity above its baseline number without prior application and approval of the facility expansion as required under Stark.
- Referrals by physicians in a group practice in a location that does not qualify as the "same building" or "centralized building" as typically required under Stark.
- Referrals by a physician to an entity with which the physician has a compensation arrangement that does not satisfy the writing or signature requirements of the

applicable Stark exception, as long as all of the other requirements of the exception are met (unless the other requirements have been waived under one or more of the Stark Blanket Waivers).

While no data or notification is required to be submitted to CMS in order to use the Stark Blanket Waivers, parties seeking to utilize the Stark Blanket Waivers should develop and retain records related to the use of the waivers in order to support the fact that the decision to use the waivers was for COVID-19 Purposes, and to document that each requirement of the waiver was satisfied. These records must be made available to the Secretary of the Department of Health and Human Services upon request.

At the end of the document setting forth the Stark Blanket Waivers, CMS provided two pages of examples of the application of the Stark Blanket Waivers. CMS clarified that unless a Stark Blanket Waiver expressly applies only to a specific type of entity (e.g., a home health provider), then the examples that CMS provided which reference a hospital would apply to any entity that furnishes designated health services. Finally, CMS provided the email address for individuals to use to submit inquiries about the blanket waivers, available here: 1877CallCenter@cms.hhs.gov. We note that individual waivers of sanctions under the Stark Law are still available and may be granted upon request submitted to the email address noted above. Such individual waiver requests are a good option for a party to consider if an existing or proposed arrangement does not appear to qualify for a Stark Blanket Waiver (or an existing Stark exception).

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For assistance in determining whether an existing or proposed arrangement complies with a Stark Blanket Waiver and/or for inquiries regarding individual waiver requests, please contact the authors or your regular Dorsey & Whitney LLP attorney. Dorsey is closely monitoring the rapidly evolving legal landscape related to the COVID-19 pandemic. You can access Dorsey's health law blog related to health law updates, available here. You can also access Dorsey's coronavirus resource center, which contains a wide variety of legal resources related to the coronavirus outbreak, available here.