

Stark Law Waivers Issued During the COVID-19 Outbreak

On March 30, 2020, in response to the COVID-19 pandemic, the Centers for Medicare and Medicaid Services (CMS) issued blanket waivers on certain sanctions under the physician self-referral law, also known as the “Stark Law.” These waivers were issued to provide physicians and providers greater flexibility in their fight against COVID-19 by temporarily removing restrictions on effectuating certain critical financial relationships (Stark Waivers). A summary of the scope and application of the Stark Waivers follows. CMS’s issuance of and guidance on the Stark Waivers can be found [here](#).

What is the Stark Law?

The Stark Law is a health care fraud and abuse law that:

- Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity the physician (or an immediate family member of the physician) has a financial relationship *unless* all of the requirements of an applicable exception are satisfied; and
- Prohibits health care providers from filing claims with Medicare (or billing another individual, entity, or third party payor) for DHS furnished pursuant to a prohibited referral.

Exceptions to the Stark Law are set forth in Section 1877 of the Social Security Act (Act) and 42 CFR 411.355 through 411.357. Sanctions for violations of the Stark Law are set forth in Section 1877(g) of the Act. If considering using a Stark Waiver, we recommend you first review the exceptions to determine if a potential financial relationship is already exempt under Stark Law—many financial relationships related to COVID-19 may already satisfy existing exceptions. If no exceptions apply, you should then look to the Stark Waivers (summarized below).

What Purpose do the Stark Waivers Accomplish?

The Stark Waivers seek to ensure sufficient health care services are available to meet the needs of individuals enrolled in Medicare, Medicaid, and CHIP programs during the COVID-19 pandemic by giving health care providers flexibility under Stark Law in how they can provide such services without penalty. Specifically, the Stark Waivers temporarily remove restrictions previously placed on physicians and providers for certain remuneration and referrals under the Stark Law that are “solely related to COVID-19 Purposes.”

What is a “COVID-19 Purpose”?

The Stark Waivers only apply to remuneration and referrals related to “COVID-19 Purposes.” CMS has broadly defined “COVID-19 Purposes” to include:

- “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 U.S.;
- Ensuring the ability of health care providers to address patient and community needs due to the COVID-19 outbreak in the U.S.;
- Expanding the capacity of health care providers to address patient and community needs due to the COVID-19 outbreak in the U.S.;

- Shifting the diagnosis and care of patients to appropriate alternative settings due to the COVID-19 outbreak in the U.S.; or
- Addressing medical practice or business interruption due to the COVID-19 outbreak in the U.S. in order to maintain the availability of medical care and related services for patients and the community.”

The 18 Stark Waivers

Sanctions under the Stark Act are waived for referrals and claims that relate to a “COVID-19 Purpose” and fall under one of the following:

- **Fair Market Value Requirements for Services** – remuneration from an entity to a physician (or an immediate family member of a physician) for services rendered by the physician (or an immediate family member of a physician) for the entity above or below fair market value.
- **Fair Market Value Requirements for Real Property Leases** – rental charges paid by an entity to a physician (or an immediate family member of a physician) for lease of office space below fair market value.
- **Fair Market Value Requirements for Equipment Leases** – rental charges paid by an entity to a physician (or an immediate family member of a physician) for a lease of equipment below fair market value.
- **Fair Market Value Requirements for Purchases** – remuneration from an entity to a physician (or an immediate family member of a physician) for items or services purchased below fair market value.
- **Rental Charges for Leased Real Property** – rental charges paid by a physician (or an immediate family member of a physician) to an entity for lease of office space below fair market value.
- **Rental Charges for Equipment** – rental charges paid by a physician (or an immediate family member of a physician) to an entity for equipment below fair market value.
- **Fees for Use of Premise, Items, and Services** – remuneration from a physician (or an immediate family member of a physician) for use of an entity’s premises, items, or services.
- **Benefit-Based Payment** – remuneration from a hospital to a physician in the form of medical staff incidental benefits that exceed the limit set forth in 42 CFR 411.357(m)(5).
- **Nonmonetary Compensation** – remuneration from an entity to a physician (or an immediate family member of the physician) in the form of nonmonetary compensation that exceeds the limits set forth in 42 CFR 411.357(k)(1).
- **Loans to Physicians** – remuneration from an entity to a physician (or an immediate family member of a physician) resulting from a loan to the physician (or an immediate family member of a 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.
- **Loans from Physicians** – remuneration from a physician (or an immediate family member of 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.
- **Referrals by Physician Owners of Expanded Hospitals** – the referral a physician owner of a hospital that temporarily expands its facility capacity above the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010, without prior application and approval.
- **Referrals by Physician Owners of Converted Ambulatory Surgical Centers** – referrals by physician owners of certain hospitals that converted from physician-owned ambulatory surgical centers to hospitals on or after March 1, 2020.
- **Referral to Home Health Agency** – the referral by a physician of a Medicare beneficiary for the provision of DHS to a home health agency: (1) that does not qualify as a rural provider; and (2) in which the physician (or an immediate family member of the physician) has an ownership or investment interest.
- **Referral by Group Practice to Other Location** – the referral by a physician in a group practice for medically necessary DHS furnished by the group practice in a location that does not qualify as a “same building” or a “centralized building.”
- **Referral by Group Practice for In-Home Care by Office Physician** – the referral by a physician in a group practice for medically necessary DHS furnished by the group practice to a patient in his or her private home, an assisted living facility, or independent living facility where the referring physician’s principal medical practice does not consist of treating patients in their private homes.
- **Rural Area Referrals to Physician’s Family-Owned Entity** – the referral by a physician to an entity with which the physician’s immediate family member has a financial relationship if the patient who is referred resides in a rural area.

- **Compensation Arrangements that do not Satisfy Writing and Signature Requirements** – referrals by a physician to an entity with whom the physician (or an immediate family member of the physician) has a compensation arrangement that does not satisfy the writing or signature requirement(s) of an applicable exception, but satisfies each other requirement of the applicable exception, unless such requirement is waived under one or more of the blanket waivers set forth above.

Notice and Record-Keeping Requirements

No notice to CMS is required to use a Stark Waiver. However, CMS encourages parties to develop and maintain records regarding any arrangements made pursuant to a Stark Waiver that can be provided to the Secretary of HHS upon request.

Modifications and Additional Waivers

The Secretary of HHS may revise the Stark Waivers from time to time to narrow, expand, or terminate any waivers. All modifications will be effective on a prospective basis only. CMS may also issue additional waivers. We will keep track of modification and additions to the Stark Waivers and alert you if any changes occur.

Duration of Waivers

The Stark Waivers are effective retroactively to March 1, 2020 and will terminate immediately as of the end of the public health emergency. Accordingly, we recommend you proactively plan for the termination of all arrangements made pursuant to a Stark Waiver.

Examples of Stark Waiver Application

For examples of how the Stark Waivers can be used in response to the COVID-19 pandemic, see the list provided by CMS [here](#).

What Affect Do the Stark Waivers Have on Federal Anti-kickback Laws?

On April 3, 2020, the Office of Inspector General (OIG) issued a Policy Statement to notify interested parties that it will not impose administrative sanctions under the federal Anti-Kickback Statute for certain remuneration related to COVID-19 covered by the first 11 of the 18 Stark Waivers for conduct occurring on or after April 3, 2020. Like the Stark Waivers, this policy will terminate immediately at the end of the public health emergency. The Policy Statement can be found [here](#).

Individual Waivers

Individual waivers of Stark Law sanctions under section 1877(g) of the Act that are not covered by the Stark Waivers may be granted upon request. For more information on how to submit an individual waiver request, visit this [link](#).

Our Chambliss team continues to monitor health care developments and other legal impacts of the COVID-19 pandemic. Please contact [Courtney Keehan](#), [Doug Griswold](#), or your relationship attorney if you have questions or need additional information.

Visit our COVID-19 Insight Center for our latest legislative and legal updates, articles, and resources.

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