Temporary Stark Law waivers during COVID-19

On March 30, 2020, the Secretary of Health and Human Services (HHS) issued blanket waivers (PDF) of the Physician Self-Referral Law (Stark Law). The waivers are retroactive to March 1, 2020, apply nationwide and will remain in effect for the duration of the public health emergency (PHE).

On April 21, 2020, the Centers for Medicare & Medicaid Services (CMS) issued guidance on the scope and application (PDF) of the blanket waivers to the Stark Law. Additionally, the HHS, Office of Inspector General (OIG) issued a FAQ guide to explain its administrative enforcement authorities to arrangements directly connected to the COVID-19 PHE.

As a result of the COVID-19 pandemic, the AMA has, and will continue to, develop resources for physician practices regarding temporary changes to the Stark Law and Anti-Kickback Statute (AKS). As these changes continue to evolve, the AMA will evaluate and provide timely updates to our AMA members.

5 things to know

1. Must be related to COVID-19 purposes

The blanket waivers of the Stark Law do not suspend the application of the Stark Law; rather, they temporarily exempt from sanctions certain arrangements that are “solely related” to COVID-19 purposes.

2. What are COVID-19 purposes?

- The 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.
● 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.

3. The Stark Law blanket waivers exempt 18 types of remuneration and referrals

These include the following (this list is not exhaustive):

Remuneration

● **Personal services**: Remuneration from an entity to a physician that is above or below the fair market value (FMV) for services personally performed by the physician to the entity.
● **Office space**: Rental charges paid by an entity to a physician that are below FMV for the entity’s lease of office space. Rental charges paid by a physician to an entity that are below FMV for the physician’s lease of office space from the entity.

Referrals

● **Referral by a physician to a home health agency**: The referral by a physician of a Medicare beneficiary for the provision of designated health care services (DHS) to a home health agency: (1) that does not qualify as a rural provider; and (2) in which the physician has an ownership or investment interest.
● **In-office ancillary services**: 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 “centralized building.”

4. A good faith standard

The Stark Law blanket waivers impose a good faith standard. Meaning, CMS and the OIG may examine the application of the waivers to each arrangement to ensure that parties are not using them in an attempt to conceal or circumvent otherwise fraudulent conduct. Although the blanket waivers do not require the submission of specific documentation or notice to HHS in advance of their use, HHS encourages parties to develop and maintain records reflecting the use of the waivers.

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5. No AKS waivers

The OIG has not indicated that it intends to issue Anti-Kickback Statute (AKS) waivers. Instead the OIG issued a policy statement (PDF) on April 3, 2020, that stated it would not impose sanctions under the AKS on arrangements that satisfied the Stark Law blanket waivers.

Note: Please consider consulting with an attorney to obtain guidance relating to your specific situation.

Other key questions

What are the practical implications of the waivers?

During and after the COVID-19 PHE has ended, parties will want to maintain robust compliance efforts to document the waiver applicable to each arrangement and the valid COVID-19 purpose justifying the use of the waiver. All parties to an arrangement should maintain appropriate documentation to support the waiver requirements. Remember, the waivers remain in effect only during the COVID-19 PHE.

When the PHE expires, so do the temporary waivers. As a result, following the pandemic, parties must ensure that all of their relationships return to Stark Law compliance.

How is the AMA advocating?

The AMA supports CMS' indication that any revisions to these blanket waivers, and any termination of the blanket waivers, will be effective on a prospective basis only. However, the AMA is planning to urge HHS and CMS to provide a grace period after expiration of the PHE to ensure physician practices have sufficient time to unwind any arrangements that fall under the blanket waivers without running afoul of strict liability compliance under the Stark Law.

Specifically, the AMA is planning to recommend that HHS maintain the Stark Law waiver flexibilities until the end of the calendar year in which the COVID-19 PHE ends. As a result, for example, physician practices who are renting equipment or space below fair market value will need sufficient time to make alternative arrangements depending on the needs of the patients in the community and their financial situation.

Contact
Parties may contact CMS directly with questions regarding the Stark Law waivers. CMS has indicated that all requests should be sent to 1877CallCenter@cms.hhs.gov and include the words “Request for 1877(g) Waiver” in the subject line. All requests should include the following minimum information:

- Name and address of requesting entity
- Name, phone number and email address of person designated to represent the entity
- CCN or TIN
- Nature of request

Disclaimer: The information and guidance provided in this document is believed to be current at the time of posting or most recent update as noted above. This information is not intended to be and should not be construed to be or relied upon as, legal, financial, or consulting advice. Consider consulting with an attorney to obtain guidance relating to your specific situation.

1 The two prerequisites that must be met before the Secretary of HHS can invoke waiver authority were satisfied as of March 13, 2020, but the blanket waivers were made retroactive to March 1. The two prerequisites that must be met before the Secretary of HHS may invoke waiver authority are: 1) the President must have declared an emergency or disaster under either the Stafford Act or the National Emergencies Act, and 2) the Secretary of HHS must have declared a Public Health Emergency under section 319 of the Public Health Service Act.