

Blog Post

Limited Stark and Anti-Kickback Sanction Waivers Issued for Provider Payments During the Pandemic

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The COVID-19 pandemic has led to urgent changes to how and where healthcare services are delivered. These changes could require expedited entry into new or modified arrangements for the delivery of essential healthcare goods and services, creating potential conflicts with the Stark Law (Section 1877 of the Social Security Act) and its regulations and potential Office of Inspector General (OIG) sanctions pursuant to the federal Anti-Kickback Statute. As a result, the Secretary of the Department of Health and Human Services (HHS) and the OIG will not impose certain sanctions during the COVID-19 pandemic. These waivers of sanctions are limited in scope and will expire at the end of the emergency declaration.

Stark Law Blanket Waivers

Certain remuneration and referral practices that ordinarily would have violated the Stark Law will be temporarily waived (including related sanctions) or modified by the Blanket Waivers of Section 1877(g) of the Social Security Act issued by the Secretary of HHS on March 30, 2020 (the [Blanket Waivers](#)). The Blanket Waivers apply only to financial relationships and referrals that are related to the national emergency that is the COVID-19 outbreak in the United States. These waivers are retroactive to March 1, 2020 and are effective through the end of

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the emergency declaration. Arrangements that do not meet an exception to the Stark Law, but do satisfy all of the conditions of a Blanket Waiver, will not be subject to sanctions for such noncompliance.

Blanket Waiver Requirements for Remuneration

The Blanket Waivers address both remuneration and referral arrangements. However, only those waivers addressing remuneration will be discussed here. If a provider intends to enter into a temporary arrangement that does not comply with the Stark Law, the provider should determine whether a specific Blanket Waiver is applicable and conform the arrangement to the specific criteria. Generally, to be eligible for a waiver the remuneration must be:

1. Furnished in good faith;
2. Absent fraud or abuse;
3. Solely related to “COVID-19 Purposes,” as defined in the Blanket Waivers;
4. Carefully documented, as records must be made available to the Secretary of HHS upon request;
5. Directly between an entity that furnishes designated health services (as defined in the Stark regulations), and (i) a physician or the physician organization in whose shoes the physician stands (as defined in the Stark regulations) or (ii) the physician’s immediate family member (the Physician’s Family); and
6. Related to one of the following:
 - *Personally Performed Services*

Remuneration from an entity to a physician or the Physician’s Family for services personally performed by the physician, or the Physician’s Family, that are above or below fair market value.

- *Lease of Office Space*

Remuneration between an entity and a physician or the Physician's Family for the lease of space that is *below* fair market value.

- *Lease of Equipment*

Remuneration between an entity and a physician or the Physician's Family for the lease of equipment that is *below* fair market value.

- *Items or Services*

Remuneration between an entity and a physician or the Physician's Family for purchased items or services that are *below* fair market value.

- *Use of Premises*

Remuneration from a physician or the Physician's Family to an entity for the use of the entity's premises that are *below* fair market value.

- *Loans to a Physician*

Remuneration from an entity to a physician or the Physician's Family resulting from a loan to the physician or the Physician's Family: (1) with an interest rate *below* fair market value; or (2) 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 to an Entity*

Remuneration from a physician or the Physician's Family resulting from a loan to the entity: (1) with an interest rate *below* fair market value; or (2) on terms that are unavailable from a lender that is not in a position to generate business for the physician or the Physician's Family.

- *Medical Staff Incidental Benefits*

Remuneration from a hospital to a physician, in the form of medical staff incidental benefits, in an amount that exceeds the limits set forth in 42 CFR 411.357(m)(5), which is less than \$36 for each occurrence of the benefit in Calendar Year 2020 (see CPI-U Updates).

- *Non-Monetary Compensation*

Remuneration from an entity to a physician, or the Physician's Family, in the form of nonmonetary compensation, that exceeds the limit set forth in 42 CFR 411.357(k)(1), which is an aggregate amount of \$423 for Calendar Year 2020.

Federal Anti-Kickback Statute Policy Statement

In addition to the Blanket Waivers issued by HHS, the OIG issued a complementary Policy Statement. The OIG indicated that it would not impose administrative sanctions related to the federal Anti-Kickback Statute for remuneration that meets the criteria of an applicable Blanket Waiver. Remuneration arising from a COVID-19 related arrangement will not be subject to the OIG's administrative sanctions if it satisfies all of the requirements set forth in the applicable Blanket Waiver.

The Policy Statement does not extend to arrangements implicated by the federal Anti-Kickback Statute but not addressed by the Blanket Waivers. For instance, the Policy Statement does not apply to direct financial relationships between providers when no physician is involved.

The Policy Statement regarding administrative sanctions will apply to conduct occurring in conformance with the Blanket Waivers on or after

April 3, 2020, and shall be valid through the end of the emergency declaration.

Going Forward

HHS and the OIG put in place these measures to assist providers solely during the COVID-19 pandemic. Arrangements entered into during this period of the national pandemic that are non-compliant with the Stark Law should expire at the end of the emergency declaration. At that time, they will be required to comply with an applicable Stark Law exception. For additional guidance on the transition of arrangements entered into pursuant to Blanket Waivers from the period covered by the emergency declaration to the post-termination period, please review the [Explanatory Guidance](#) issued by DHHS on April 21, 2020 or seek legal assistance.

This information is intended to inform firm clients and friends about legal developments, including recent decisions of various courts and administrative bodies. Nothing in this Practice Update should be construed as legal advice or a legal opinion, and readers should not act upon the information contained in this Practice Update without seeking the advice of legal counsel. Prior results do not guarantee a similar outcome.