

CMS Issues Explanatory Guidance on Blanket Stark Law Waivers

Client Alert

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The Centers for Medicare & Medicaid Services (CMS) has provided explanatory guidance with respect to several blanket waivers of certain provisions of the Stark Law the CMS previously issued, which were summarized in our April 2, 2020 [Client Alert](#).

It should be noted that although the Office of the Inspector General of the U.S. Department of Health and Human Services has issued a Policy Statement regarding certain waivers of the federal Anti-Kickback Statute (AKS) that, in some ways, parrots some of the blanket waivers of certain provisions of the Stark Law, the explanatory guidance issued by CMS, as outlined below, applies only to blanket waivers of the Stark Law and does not apply to the AKS.

As always, these actions must be reconciled with any applicable state self-referral laws as CMS does not have the authority to waive state laws.

Compliance with Non-Waived Requirements of an Applicable Exception

As a reminder, the Stark Law is a strict liability law. Therefore, financial relationships or referrals must still satisfy all non-waived requirements of an applicable exception in order to avoid the referral and billing prohibitions of the Stark Law. The failure of a financial relationship or specific referral to satisfy one or more of the other requirements of an applicable exception would trigger the Stark Law's referral and billing prohibitions. Many of the Stark Law exceptions require that arrangements be commercially reasonable, that arrangements clearly specify what is being provided, and that the compensation be set in advance. Unless expressly waived by a blanket waiver, these requirements are not waived.

Amendment of Compensation Arrangements

CMS has historically interpreted and continues to interpret preamble guidance in the Fiscal Year 2009 Inpatient Prospective Payment System final rule to allow a second or subsequent amendment of the remuneration terms of a compensation arrangement, even within the first year after an initial amendment of the remuneration terms of

the arrangement, provided that:

- each time the remuneration terms are amended, all requirements of an applicable exception to the Stark Law are satisfied,
- the amended remuneration is determined before the amendment is implemented,
- the formula for the amended remuneration does not take into account the volume or value of referrals or other business generated by the referring physician, and
- the overall arrangement remains in place for at least 1 year following the amendment.

Following the expiration of the emergency period, the remuneration terms of the compensation arrangement may again be modified to return to the original terms of the arrangement or to effectuate additional necessary modifications to the arrangement, provided that:

- each time the remuneration terms are amended, all requirements of an applicable exception to the Stark Law are satisfied,
- the amended remuneration is determined before the amendment is implemented,
- the formula for the amended remuneration does not take into account the volume or value of referrals or other business generated by the referring physician, and
- the overall arrangement remains in place for at least 1 year following the amendment.

It is possible that a modification of an existing compensation arrangement could instead be analyzed as an additional compensation arrangement between or among the same parties during the term of the emergency period. For example, assume that a hospital leases office space to a physician and that the lease arrangement satisfies all requirements of 42 CFR 411.357(a). During the emergency period, the hospital wishes to provide financial support to the physician to assist with the physician's practice operating costs and ensure that medical care and related services are available to patients in the community during the emergency period. Although the hospital could modify the lease arrangement to reduce the rental charges during the emergency period, it could also enter into a separate compensation arrangement with the physician to provide the financial support without changing the remuneration terms of the lease arrangement. The parties could use the blanket waivers, if necessary, to avoid sanctions under the Stark Law for the financial support to the physician, keeping in mind that the blanket waivers will terminate when the declaration of the national emergency is no longer in effect.

Applicability of Blanket Waivers to Indirect Compensation Arrangements

The blanket waivers do not apply to indirect compensation arrangements as defined in the Stark Law. Parties may request an individual waiver of the sanctions under the Stark Law related to remuneration that constitutes an indirect compensation arrangement, but a waiver for indirect compensation arrangements may not be necessary in most instances. A physician who stands in the shoes of their physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. All physicians with non-titular ownership or investment interests stand in the shoes of their physician organizations. Any other physician in a physician organization is permitted to stand in the shoes of the physician organization. Thus, when a compensation arrangement for which parties seek protection under the blanket waivers is directly between an entity and a physician organization, the remuneration is deemed to be directly between the entity

and: (1) each non-titular physician owner of the physician organization; and (2) each non-owner physician in the physician organization whom the parties treat as permissively standing in the shoes of the physician organization.

Repayment Options for Loans between a DHS Entity and a Physician (or the Immediate Family Member of a Physician)

Besides the blanket waivers that address remuneration in the form of a loan with an interest rate below fair market value or on terms that are unavailable from a lender that is not in a position to make referrals to or generate business for the party making the loan, the isolated transactions exception and the fair market value exception to the Stark Law may also apply to certain loan arrangements between entities and physicians.

This is important, as the blanket waivers do not waive sanctions related to repayment of the loan. Nothing in either of those exceptions requires cash payments to satisfy a borrower's debt to a lender. However, the blanket waivers do not waive sanctions for referrals and claims related to the repayment of the loan. Thus, the aggregate value of in-kind payments must be consistent with the amount of the loan balance being reduced through the in-kind payments. In addition, compensation arrangements involving in-kind payments must be commercially reasonable. They may also implicate the AKS. The maintenance of a medical practice and continuing to serve patients in the community where an entity is located may constitute a physician's in-kind loan repayment to the entity depending on the applicable facts and circumstances of the parties.

CMS has previously stated that a physician's relocation to a community to establish a medical practice is not properly viewed as a benefit to a recruiting hospital, but rather as a benefit to the community. The exception for retention payments in underserved areas under the Stark Law may be available to protect remuneration from a hospital to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital.

Repayment of Loans, Rent Abatement, or Other Amounts Due Following the End of the Emergency Period

The completion of obligations under an arrangement after its expiration or termination is common and need not result in noncompliance with the Stark Law. For example, assume that a compensation arrangement calls for payment for a physician's services upon the provision of documentation that the services were furnished and the presentation of an invoice for payment. Assume also that the arrangement expired by its terms on December 31, 2019. The entity may not receive documentation of and invoices for services furnished on or before December 31, 2019 until after such date. The entity may make appropriate payments for previously furnished services after the expiration of the arrangement. Appropriate repayment terms agreed to prior to the termination of the blanket waivers may continue beyond the termination of the blanket waivers without running afoul of the Stark Law. However, any disbursement of loan proceeds after the termination of the blanket waivers, or additional remuneration after the termination of the blanket waivers for office space, equipment, items, or services furnished by or to an entity or physician, must satisfy all requirements of an applicable exception.

Restructuring of Existing Recruitment Arrangements with Income Guarantees

In CMS advisory opinion CMS-AO-2007-01, CMS stated that parties to a physician recruitment arrangement should not be able to amend their arrangement after it has commenced to provide for additional (or potentially additional) compensation to the recruited physician. None of the blanket waivers change this core requirement of the Stark Law exception for physician recruitment, and the analysis set forth in advisory opinion CMS-AO-2007-

01 remains CMS policy. However, other blanket waivers may be available to waive sanctions of the Stark Law for remuneration from a hospital (or other entity) to assist a physician whose medical practice experiences interruption due to COVID-19 in order to maintain the availability of medical care and related services for patients and the community. For example, a blanket waiver waives sanctions under the Stark Law for referrals and claims related to rental charges that are below fair market value for the physician's lease of office space from an entity, and another blanket waiver waives sanctions under the Stark Law for referrals and claims related to 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.