

Compliance Today – December 2020 Challenges of maintaining compliant provider arrangements during and after a public health emergency

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The COVID-19 pandemic has required many healthcare providers to enter quickly into new or modified arrangements for the delivery of essential healthcare goods and services. Some of these arrangements may conflict with the Stark Law (Section 1877 of the Social Security Act) and its regulations and may expose providers to administrative sanctions by the Office of Inspector General (OIG) pursuant to the federal Anti-Kickback Statute (AKS). In response to the unique circumstances of the pandemic, the secretary of the Department of Health & Human Services (HHS) and the OIG published temporary waivers^[1] and a policy statement^[2] to provide compliance assistance during the COVID-19 pandemic. The blanket waivers and OIG policy statement will be in effect temporarily, until the end of the federal public health emergency declared in response to the COVID-19 pandemic (the emergency period).^[3] This article provides general guidance on the relationship between the blanket waivers granted by HHS, the policy statement published by the OIG, and the return to full compliance upon the conclusion of the emergency period.

Compliance during the pandemic

Arrangements entered during the emergency period that do not meet an exception to the Stark Law but satisfy all of the conditions of one of the blanket waivers to the Stark Law issued by the HHS secretary will not be subject to sanctions for such noncompliance. Compliance officers should ensure their organizations know that the waivers are available and understand the requirements that must be satisfied if the organization elects to take advantage of a blanket waiver. The organization, through counsel and its compliance officer, would be well advised to ensure that the temporary arrangement will expire and that a mechanism is in place to resume full compliance upon expiration.

Satisfy the blanket waiver requirements

If a provider intends to enter into a temporary arrangement that does not comply with the Stark Law during the emergency period, the compliance officer should determine whether a specific blanket waiver is applicable and ensure conformance of the arrangement to the waiver's specific criteria.

The blanket waivers address both remuneration and referral arrangements that are related to the emergency period. However, only those waivers addressing remuneration will be discussed here. These waivers are retroactive to March 1, 2020, and are effective through the end of the emergency period. Generally, to meet the criteria to be eligible for a blanket waiver, the remuneration must be:

- Furnished in good faith;
- Absent of fraud or abuse;

- Solely related to “COVID-19 Purposes,” as defined in the blanket waivers;
- Carefully documented, as records must be made available to the HHS secretary upon request;
- An arrangement 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 (physician’s family); and
- 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:^[4] 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 C.F.R. § 411.357(m)(5) , which is less than \$36 for each occurrence of the benefit in calendar year 2020.^[5]
 - Nonmonetary 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 C.F.R. § 411.357(k)(1) , which is an aggregate amount of \$423 for calendar year 2020.

Adhere to the federal AKS OIG policy statement

In addition to the blanket waivers issued by the HHS, OIG issued a complementary policy statement that indicates that it will not impose administrative sanctions related to the federal AKS for remuneration arising from a COVID-19–related arrangement that satisfies all of the criteria of one of the blanket waivers.^[6] The policy statement does not extend to arrangements implicated by the federal AKS but not addressed by the above blanket waivers. The policy statement only applies to arrangements that may otherwise violate the Stark Law, so a

physician must be a party to an arrangement before the OIG's statement will apply.

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.

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