



COVID-19 Update: CMS issues explanatory guidance on Stark Law blanket waivers

April 28, 2020

On April 21, 2020, the Centers for Medicare & Medicaid Services (CMS) issued [additional guidance](#) explaining the scope and application of the Stark Law blanket waivers to certain financial relationships. CMS issued the Stark Law blanket waivers on March 30, 2020, in response to the COVID-19 pandemic. The [blanket waivers](#) are effective March 1, 2020, to waive sanctions under the Stark Law for certain referrals and claims that would otherwise violate the law because they fail to satisfy one or more requirements of an applicable Stark Law exception.

The explanatory guidance clarifies a number of concerns industry stakeholders have raised with CMS about using the waivers. CMS also points out that reliance on a blanket waiver may not be necessary, because many arrangements related to COVID-19 purposes can satisfy an existing exception and, as a result, would not need to rely on a waiver. However, parties relying on the Stark Law blanket waivers should take some comfort in CMS' statement that it will work with the Department of Justice to address False Claims Act whistleblower lawsuits when parties have a good faith belief that their arrangement is covered by a blanket waiver.

The CMS guidance offers helpful insight into how parties can use the blanket waivers to modify existing arrangements and enter into new arrangements to address challenging circumstances during the COVID-19 emergency. Specifically, it clarifies several points related to amendments, indirect compensation, loans and physician recruitment.

Amendments

- Parties can use the blanket waivers to amend compensation terms during the COVID-19 emergency, even if the amendment is made during the first year after another amendment was made.
- Parties can amend arrangements so long as:
 - the amendment satisfies all terms of an applicable exception (including all non-waived requirements);
 - the compensation formula is determined before the amendment is implemented and does not take into account the volume or value of referrals or other business generated by the referring physician;
 - the amendment remains in place for at least one year.
- After the emergency is over, compensation terms may return to the original terms, or even change to different terms, as long as each modification complies with all requirements of an applicable exception.
- Instead of amending an existing compensation arrangement, parties could potentially enter into a new compensation arrangement using a blanket waiver. For example, instead of modifying an existing hospital office lease with a physician to reduce the rent, the hospital could enter into a new arrangement with the physician to provide financial support, such as a loan.

Indirect compensation

Although the blanket waivers do not apply to indirect financial arrangements, parties to these arrangements are not out of luck. These parties can use the blanket waivers for direct financial relationships by permitting non-owner physicians in a physician organization to stand in the shoes of the physician organization, thereby creating a direct financial arrangement.

Loans

- Blanket waivers allowing loans with below fair market value interest rates or other terms unavailable from a lender not in a position to refer do not require repayment in cash.
- In-kind repayment is permitted, but the value of in-kind payments should generally be consistent with the amount of the loan balance and commercially reasonable under the circumstances. For example, CMS suggests that maintaining a medical practice and continuing to serve patients in the community where an entity is located could be a physician's in-kind loan repayment, depending on the facts and circumstances.
- Parties may continue loan repayment after the COVID-19 emergency is over under terms agreed upon while the blanket waivers are in effect. However, any loan disbursements after the blanket waivers are terminated must satisfy all requirements of an applicable exception.

Physician recruitment

Although none of the blanket waivers are available to permit parties to amend a physician recruitment agreement with an income guarantee to increase the amount of compensation or to extend an income guarantee period, the available blanket waivers could still be used to provide financial support to the recruited physician. For example, they could use the blanket waiver permitting a reduction in rent or the waiver permitting a loan to a physician.

Webinar Announcement:

Bricker will be hosting a webinar on May 6, 2020, to discuss the Stark Law blanket waivers and Anti-Kickback Statute compliance during the COVID-19 public health emergency. To learn more and register, click [here](#).

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