

CMS Clarifies Stark Law Blanket Waivers

Insights

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On April 21, 2020, CMS issued [Explanatory Guidance](#) to clarify the Stark law blanket waivers issued on March 30. This new guidance addresses certain open questions regarding the waivers, underscoring the agency's intent to provide flexibility to parties structuring physician financial relationships in response to the COVID-19 outbreak. This guidance also answers lingering questions regarding amendments of existing agreements in light of the "one year" requirements under the lease and personal services arrangements exceptions, and the similar fair market value compensation exception requirement that the parties enter into only one arrangement for the same items or services during the course of a year.

Highlights from the Explanatory Guidance:

- *Compliance with Non-Waived Requirements of an Applicable Exception*: The Explanatory Guidance confirms that financial relationships or referrals, as applicable, must satisfy all of the non-waived requirements of the applicable exception to avoid triggering the Stark law's referral and billing prohibitions. CMS also identifies the applicable exceptions for each of the blanket waivers.
- *Amendment of Compensation Arrangements*: The Explanatory Guidance clarifies that the remuneration terms of an existing compensation arrangement may be amended, even during the first year of the arrangement, so long as the "overall arrangement remains in place for a least 1 year following the amendment." This commentary is significant both in the context of the blanket waiver application and the use of the exceptions which reference one-year timeframes more generally. The Explanatory Guidance also encourages providers to consider whether COVID-19 arrangements should be viewed as "modifications" of existing arrangements or as new arrangements between the same parties.
- *Applicability to Indirect Compensation Arrangements*: The Explanatory Guidance confirms that the waivers do not apply to indirect compensation arrangements. CMS notes that parties can request an individual waiver as needed, but that may not be necessary in most instances, given the ability (or, in some cases, the requirement) for a physician to "stand in the shoes" of his or her physician organization, which must have a direct compensation arrangement with the entity in question.
- *Repayment Options for Loans between a DHS Entity and a Physician (or Immediate Family Member of a Physician)*: Repayment need not be in cash. It can be in-kind, e.g., items and/or services, or (potentially) a commitment

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CHARLES B. OPPENHEIM
Partner
Los Angeles
San Francisco

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- *Repayment of Loans, Rent Abatement, or Other Amounts Due Following the End of the Emergency Period*: As long as the loan terms are agreed to and the loan proceeds provided while the waiver is in effect, it is permissible for the repayment period to continue after the waiver ends, even if the terms would not meet a non-waived exception.
- *Restructuring Existing Recruiting Arrangements with Income Guarantees*: The Explanatory Guidance confirms that the blanket waivers do not provide protection for providers seeking to modify existing physician recruitment arrangements in order to provide additional (or potentially additional) compensation. CMS does suggest that providers consider whether there are blanket waivers available that would allow a hospital to assist a physician with the impacts of practice interruption – including a loan with a below market interest rate or rental charges pursuant to a lease at below fair market value.
- *Potential Risk Exposure When Relying on a Waiver*: Despite best efforts to structure an arrangement so that it is covered by a waiver, when the current public health emergency ends, there are likely to be challenges against actions taken by hospitals and other entities that provide designated health services with respect to financial relationships with physicians (in addition to other expected litigation, such as challenges with respect to eligibility for, and appropriate use, of stimulus funds). In the Stark law blanket waivers, CMS also made clear that the waivers would not apply if there is a government determination of fraud and abuse. Although the risk associated with such challenges cannot be eliminated, CMS does provide some comfort in its Explanatory Guidance with respect to the Stark law blanket waivers, stating that it will “work with the Department of Justice to address False Claims Act relator suits where parties using the blanket waivers have a good faith belief that their remuneration or referrals are covered by a blanket waiver.”

HLB’s Coronavirus Task Force is monitoring developments closely. For federal and state resources on COVID-19, please refer to our [COVID-19 Resource Page](#).

For further information, please contact [Charles Oppenheim](#), [David Henninger](#), or [Nina Adatia Marsden](#) in Los Angeles, [Amy Joseph](#) in Boston, Ben Durie, [Paul Smith](#) or [Stephanie Gross](#) in San Francisco, or your regular Hooper, Lundy & Bookman contact.

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