DORSEY
DORSEY + WHITNEY LLP

CMS Issues Explanatory Guidance on Stark Law Blanket Waivers

April 29, 2020 – Dorsey Health Law
by Alissa Smith, Laura B. Morgan, and Charis Zimmick

As we explained in our prior blog post, on March 30, 2020, the Centers for Medicare & Medicaid Services ("CMS") issued certain blanket waivers of sanctions under the federal physician self-referral law (or "Stark Law") for "COVID-19 Purposes" (the "Stark Blanket Waivers"), which are available here. On April 21, 2020, CMS issued explanatory guidance, available here, on the scope and application of the Stark Blanket Waivers to certain financial relationships (the "Explanatory Guidance").

In addition to answering a variety of questions raised by the initial announcement of the Stark Blanket Waivers, the Explanatory Guidance provides an important reassurance to stakeholders. CMS states: "The Secretary 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." Despite this reassurance, however, it is crucial that parties seeking to rely on a Stark Blanket Waiver ensure that their arrangement, in fact, relates to "COVID-19 Purposes" (as defined in the Stark Blanket Waivers document), falls within the parameters of a specifically enumerated waiver within the Stark Blanket Waivers document, and that all non-waived requirements of an applicable Stark Law exception are met. We also note that, as CMS reminds parties in the Explanatory Guidance, relying on a Stark Blanket Waiver may not be necessary for certain arrangements related to COVID-19 Purposes, if these arrangements satisfy the requirements of an existing Stark Law exception.
The following information summarizes the Explanatory Guidance.

A. Compliance with Non-Waived Requirements of an Applicable Exception

Many of the Stark Blanket Waivers eliminate or alter some, but not all, of the existing requirements of particular Stark Law exceptions. CMS warns that financial relationships or referrals must satisfy all non-waived requirements of an applicable exception in order to avoid implicating the Stark Law's referral and billing prohibitions. We note that this includes, for example, meeting the "set in advance" requirement of applicable compensation exceptions, as this requirement is not waived by any of the Stark Blanket

Related People

- Alissa Smith

Related Capabilities

- Healthcare & Life Sciences
- Healthcare Transactions & Regulations
- Healthcare Litigation
- Medical Devices

Waivers.

B. Amendment of Compensation Arrangements

The Explanatory Guidance clarifies when parties may modify the remuneration terms of an existing arrangement during the COVID-19 emergency period, and whether such terms can be amended during the emergency period and again at the conclusion of the emergency period to return to the original terms. This guidance applies when parties are relying on a compensation exception that has both a one-year term requirement and a "set in advance" requirement (such as the personal services arrangements exception).

CMS points to the preamble guidance in the Fiscal Year 2009 Inpatient Prospective Payment System final rule ("FY 2009 IPPS Rule"), which CMS interprets as allowing for a second or subsequent amendment of the compensation terms of an arrangement, even within the first year of an initial amendment of those terms, as long as each time those terms are amended, "all requirements of an applicable exception 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."

CMS reiterates that if parties amend a compensation arrangement during the emergency period, all non-waived requirements of an applicable exception must be met. The compensation terms of the arrangement may again be amended after the public health emergency is over. This further amendment may restore the original terms of the arrangement or make additional changes, as long as each of the criteria from the FY 2009 IPPS Rule (described above) are met. Finally, CMS points out that a modification of an existing arrangement could instead be analyzed as an additional compensation arrangement, for which the parties could use the Stark Blanket Waivers (if all applicable requirements are met).

C. Applicability of Blanket Waivers to Indirect Compensation Arrangements

The Explanatory Guidance states that the Stark Blanket Waivers do not apply to indirect compensation arrangements, and only apply to direct compensation arrangements. Parties can, however, seek an individual waiver of sanctions related to indirect compensation arrangements. The Explanatory Guidance goes on to note that many compensation arrangements that may appear to be indirect may be analyzed as direct compensation arrangements under the "stand in the shoes" provisions of the Stark Law.

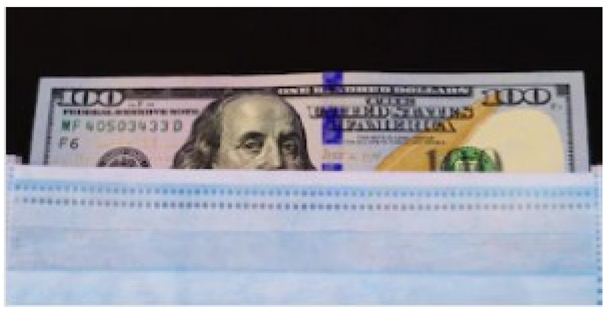
D. Repayment Options for Loans between a DHS Entity and a Physician (or the

Immediate Family Member of a Physician)

Two Stark Blanket Waivers (waivers #10 and #11) involve 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. CMS states that these waivers do not require cash payments to the lender to satisfy a borrower's debt. Loans may be repaid through in-kind payments, as long as the aggregate value of the in-kind payments is consistent with the amount of the loan and the arrangement is commercially reasonable. CMS provides that an example in-kind payment could be the maintenance of a medical practice and continuing to serve patients in the community where the entity is located.

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

CMS clarified that, if parties use the Stark Blanket Waivers such as the loan arrangements described above, repayment obligations do not need to be completed prior to the termination of the Stark Blanket Waivers (which will be at the end of the public health emergency that was declared related to the COVID-19 outbreak). Many parties expressed concern that, after the termination of the Stark Blanket Waivers, the compensation arrangements entered into would no longer satisfy the requirements of an applicable exception because the interest charges or other charged amounts would not be consistent with the fair market value of the remuneration provided. The Explanatory Guidance provides that appropriate repayment terms agreed to before the termination of the Stark Blanket Waivers may continue beyond the termination of the waivers. However, disbursement of loan proceeds or additional remuneration after the termination of the Stark Blanket Waivers must satisfy all requirements of the applicable Stark exception.



F. Restructuring of Existing Recruitment Arrangements with Income Guarantees

CMS also responded to inquiries about the extension or restructuring of existing physician recruitment arrangements, such as whether a hospital could extend an income guarantee to address a recruited physician's medical practice interruption due to the COVID-19 pandemic. The Explanatory Guidance states that CMS maintains its position that, under the Stark Law exception for physician recruitment, the terms of a recruitment arrangement cannot be altered once the physician has relocated their practice. Some Stark Blanket Waivers, however, may be available for remuneration from a hospital (or other entity) to assist a relocated physician whose medical practice is disrupted due to the pandemic in order to maintain the availability of medical care and related services for patients and the community.

* * *

For help determining whether an existing or proposed arrangement complies with a Stark Blanket Waiver and/or for inquiries regarding individual waiver requests, please contact the authors of this post or your regular Dorsey attorney. We continue to closely monitor the legal landscape related to the COVID-19 pandemic. You can access Dorsey's health law blog providing health law updates, available here. You can also access Dorsey's coronavirus resource center, containing a wide variety of legal resources related to the coronavirus outbreak, available here.