



Stark Law and Anti-Kickback Statute Enforcement Eased During COVID-19 Crisis

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In response to COVID-19, the Centers for Medicare and Medicaid Services (CMS) issued a document setting forth a set of “[blanket waivers](#)” pertaining to compliance with the physician self-referral law, commonly known as the Stark law (42 U.S.C. § 1395nn). The blanket waivers allow for certain compensation and referral arrangements to be used in light of the COVID-19 crisis where such arrangements otherwise would result in a Stark violation, which may carry both criminal and civil penalties. In addition, Health and Human Services’ Office of Inspector General (OIG) issued a [concurrent policy statement](#) holding that the OIG will not impose administrative sanctions for a violation of the Federal anti-kickback statute (AKS) (42 U.S.C. § 1320a-7b[b]) in cases where an arrangement complies with one of a subset of the Stark blanket waivers. To sanction a party for AKS violations, the OIG can exclude them from participation in federal health care programs and impose civil monetary fines.

Stark prohibits physicians from referring Medicare patients to an entity for the provision of any “designated health services” (which include 10 categories of health care services) if the physician (or his/her immediate family member) has a financial relationship with the entity, unless the arrangement meets all requirements of a regulatory Stark exception. The AKS in general prohibits any party from knowing and willfully giving or receiving something of value with the intention of inducing referrals of business that is payable in whole or in part by a federal health care program.

In many cases, arrangements in violation of the Stark law will concurrently violate the AKS. For example, many of the Stark regulatory exceptions require that any compensation between the parties must be consistent with fair market value. In an arrangement where a physician is being paid in excess of fair market value, the facts and circumstances often indicate the excessive compensation was paid with the intent of inducing the physician to

refer patients to the source of the payment. Thus, the OIG's policy statement provides assurance to parties making use of a Stark blanket waiver that, in doing so, they are not unwittingly putting themselves at risk of AKS sanctions.

Both CMS and OIG recognize the difficult and unprecedented circumstances facing health care providers in the time of the COVID-19 crisis, and that it may not be possible for some providers to fulfill needed patient care obligations while still complying with various regulatory rules. This was the basis for the agencies taking these unique and unprecedented actions.

Blanket waivers can be issued by CMS when a determination has been made that all similarly-situated providers in an emergency area need such a waiver or modification. Otherwise, waivers are issued on an individual basis and only upon request by a specific party, which must provide justification for the waiver and the expected duration of the modification requested. In this case, the blanket waivers and the policy statement are applicable on a nationwide basis for the length of the public health emergency caused by COVID-19.

Making use of the Stark blanket waivers essentially involves a two-step process. The first is to demonstrate the arrangement is "solely related to COVID-19 Purposes." There are six enumerated "COVID-19 Purposes" described in the document, which in general are aligned with patient care circumstances – i.e., the Stark violation occurred because it was a necessary element to provide needed patient care. The second step is ensuring that the arrangement falls within one of the 18 enumerated situations to which a blanket waiver applies. The first 11 of the waivers pertain to payment in some form of remuneration being exchanged between the parties. One example is where a physician is being compensated above or below fair market value for the provision of personally-performed services. The remaining seven waivers apply to referral arrangements between the parties. Also, within the document, CMS included 20 examples of potential real-world application of the blanket waivers.

As indicated above, the AKS prohibits giving or receiving anything of value, often referred to as "prohibited remuneration," with the intention of inducing referrals. Thus, the OIG policy pertains to the

first 11 blanket waivers (since, as stated above, those waivers all pertain to remuneration) and states that any arrangement meeting one of those 11 blanket waivers will not be subject to administrative sanctions under the AKS. As for the other seven blanket waivers, the OIG indicates in the policy that it is accepting questions about the application of its administrative sanctions authority to those waivers. This suggests the OIG may see fit to advise requesting parties that it will not impose sanctions with regard to their particular arrangement, similar to the various OIG advisory opinions the agency has been issuing since 1997.

CMS's blanket waivers were issued March 30, 2020, but are retroactively effective back to March 1. Somewhat curiously, the OIG policy statement was issued April 3, 2020, and by its own terms is applicable only to conduct occurring on or after that date. Although the policy statement is not retroactive to March 1, it seems unlikely the OIG would attempt to impose sanctions on an arrangement that was compliance with a Stark blanket waiver before April 3.

Parties utilizing the blanket waivers, according to the document, "must make records relating to the use of the blanket waivers available to the Secretary of Health and Human Services upon request." Accordingly, it will be important for the parties intending to rely on a blanket waiver to sufficiently document the arrangement, including compliance with COVID-19 Purposes and the specific blanket waiver being relied upon.

Both the CMS waivers and OIG policy statement will terminate upon the expiration of the COVID-19 disaster declaration. Thus, it will be important for any parties relying on a blanket waiver to have the ability (and wherewithal) to quickly and timely unwind the arrangements in question. While it is reasonable to believe the agencies might allow some "grace period" in light of the nationwide crisis, it is unclear presently how long such a period may last. Therefore, in the absence of clear agency guidance, relying parties should be prepared to act quickly to bring those arrangements back into compliance with Stark and the AKS.

For more information, please contact [Jim Dietz](#), [Rhonda Schechter](#), [Haifeng Hong](#) or any attorney in Frost Brown Todd's [Health Care Innovation](#) industry team.

To provide guidance and support to clients as this global public-health crisis unfolds, Frost Brown Todd has created a [Coronavirus Response Team](#). Our attorneys are on hand to answer your questions and provide guidance on how to proactively prepare for and manage any coronavirus-related threats to your business operations and workforce.

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