

# UPDATE: OIG Issues COVID-19 Enforcement Policy Statement

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As noted in our recent alert (4.7.20) ([see below](#)), the Centers for Medicare & Medicaid Services (“CMS”) recently issued “[blanket waivers](#)” concerning several Stark Law requirements in response to the COVID-19 pandemic. CMS enacted the Stark Law Blanket Waivers to ensure the availability of healthcare services for patients during the current public health emergency and to allow healthcare providers to receive payment for certain claims that, without a blanket waiver, would violate the Stark Law.

On April 3, 2020, the Office of Inspector General for Health & Human Services (“OIG”) issued a similar [Policy Statement](#), also aimed at protecting patients and providing regulatory flexibility to allow healthcare providers to adequately respond to the COVID-19 pandemic. Pursuant to the Policy Statement, the OIG will “exercise its enforcement discretion not to impose administrative sanctions under the Federal anti-kickback statute for certain remuneration related to COVID-19 covered by the [Stark Law Blanket Waivers].”

Specifically, the OIG will not impose sanctions under the federal Anti-Kickback Statute with respect to conduct covered by Section II.B.(1)-(11) of the Stark Law Blanket Waivers, which relate to certain personal service arrangements, equipment and office space leases, medical staff incidental benefits, nonmonetary compensation and loan arrangements linked to “COVID-19 Purposes” (as defined in the Stark Law Blanket Waivers). The OIG’s Policy Statement applies to conduct occurring on or after April 3, 2020, and, like the Stark Law Blanket Waivers, will terminate upon the expiration or termination of the declared public health emergency.

Despite the enforcement relief granted under the Policy Statement, the OIG still advises that it will continue to investigate and prosecute fraudulent activities. Therefore, parties seeking to take advantage of the Stark Law Blanket Waivers and the OIG’s Policy Statement must be diligent in appropriately analyzing and documenting the arrangements to qualify for protection.

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## News Alert below originally posted Tuesday, April 7

### CMS Issues COVID-19 Stark Law Blanket Waivers:

On March 30, 2020, pursuant to Section 1135 of the Social Security Act, the Centers for Medicare & Medicaid Services (“CMS”) issued “[blanket waivers](#)” concerning several Stark Law requirements in response to the COVID-19 public health emergency. The blanket waivers apply nationwide and are intended to: (1) ensure the availability of healthcare services for Medicare and Medicaid beneficiaries during the current public health emergency; and (2) allow healthcare providers to receive payment for certain claims that, without a blanket waiver, would violate the Stark Law.

Generally, the Stark Law prohibits a physician from making patient referrals for certain designated health services (“DHS”) payable by Medicare to an entity that the physician (or the physician’s immediate family member) has a financial relationship with, unless a Stark Law exception applies. The blanket waivers announced on March 30 waive sanctions for certain items and services provided in good faith under arrangements that are unable to comply with an available Stark Law exception as a result of the COVID-19 pandemic. The blanket waivers apply to various financial arrangements and referrals between physicians and DHS entities. As outlined in the [blanket waiver document](#), the waivers apply to relationships including, but not limited to, personal service arrangements, equipment and office space leases, medical staff incidental benefits, nonmonetary compensation, certain loan arrangements, physician-owned hospitals and group practices.

However, the blanket waivers only apply to arrangements linked to COVID-19 Purposes, which CMS defines as:

- Diagnosis or medically necessary treatment of COVID-19 for any patient or individual, whether or not the patient or individual is diagnosed with a confirmed case of COVID-19;

- Securing the services of physicians and other healthcare practitioners and professionals, to furnish medically necessary services in response to the COVID-19 outbreak in the United States;
- Ensuring the ability of healthcare providers to address patient and community needs due to the COVID-19 outbreak;
- Expanding the capacity of healthcare providers to address patient and community needs due to the COVID-19 outbreak in the United States;
- Shifting the diagnosis and care of patients to appropriate alternative settings due to the COVID-19 outbreak in the United States; or
- Addressing medical practice or business interruption due to the COVID-19 outbreak in the United States in order to maintain the availability of medical care and related services for patients and the community.

Parties seeking to enter arrangements that fall within the blanket waivers should document use and satisfaction of the blanket waivers. Parties should also be prepared to make such documentation available to CMS upon request. The **blanket waiver document** also includes an illustrative, nonexclusive list of example arrangements and conduct that may fall within the scope of the blanket waivers. These examples may help in evaluating a particular arrangement or financial relationship. Even with the blanket waivers, parties should remember that reliance on a blanket waiver is not needed when an arrangement or financial relationship satisfies an existing Stark Law exception.

The blanket waivers are retroactive to March 1, 2020, and will remain in place until the expiration or termination of the declared public health emergency. CMS may also revise the blanket waivers and issue additional blanket waivers, as necessary, in the future. Revisions and updates to the blanket waivers will be posted on the CMS website.

Because the blanket waivers remain in place only through the declared public emergency, they are not permanent. Without extension or grandfathering by CMS, the blanket waivers will expire when the public emergency is over. At that time, parties will need to be prepared to terminate the arrangements or restructure them to comply with an appropriate Stark Law exception.

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