

# Stark Law Blanket Waivers

## **CMS to waive certain aspects of the Physician Self-Referral Law during the pandemic to ensure that sufficient health care is available to patients enrolled in Medicare, Medicaid and CHIP.**

Due to the COVID-19 national emergency, CMS has issued 18 [Blanket Waivers](#) of certain aspects of the federal Physician Self-Referral Law (the “[Stark Law](#)”), effective March 1, 2020. CMS is permitted to issue Stark Law waivers in the event of an emergency or disaster to help ensure that sufficient health care is available for patients enrolled in Medicare, Medicaid and CHIP, and that the health care providers who act in good faith but cannot comply with the Stark Law may be reimbursed and exempted from Stark Law sanctions absent any determination of fraud or abuse. The Blanket Waivers will be in place through the end of the HHS emergency declaration.

The HHS Office of Inspector General (OIG), recognizing the need for the health care industry to focus on patient care during the emergency, issued a [Policy Statement](#) stating that OIG will not impose certain administrative sanctions under the federal Anti-Kickback Statute (AKS) for certain conduct related to certain Blanket Waivers occurring on or after April 3. All conditions and definitions that apply to the Blanket Waivers apply to the OIG Policy Statement.

The following are examples of conduct that may be permitted under both the Blanket Waivers and the OIG Policy Statement, depending on the circumstances and if all conditions are met:

- A hospital pays physicians above their previously-contracted rate for furnishing professional services for COVID-19 patients in particularly hazardous or challenging environments
- To accommodate patient surge, a hospital rents office space or equipment from an independent physician practice at below fair market value or at no charge
- An entity provides free telehealth equipment to a physician practice to facilitate telehealth visits for patients who are observing social distancing or in isolation or quarantine.
- A hospital provides meals, comfort items (for example, a change of clothing), or onsite child care with a value greater than \$36 per instance to medical staff physicians who spend long hours at the hospital during the COVID-19 outbreak in the United States

A dentist contemplating a transaction with an individual or entity to whom the dentist refers patients would be prudent to:

- Consult a qualified attorney to review the transaction for Stark Law and AKS risk
- Make sure the requirements of any applicable exception, waiver or safe harbor are met and that the transaction complies with other applicable federal, state and local law
- Be alert for the HHS announcement of the termination of the emergency declaration CMS may from time to time release additional blanket waivers.

For an example, please see the agency’s [COVID-19 Emergency Declaration: Blanket Waivers for Health Care Providers](#).

The Stark Law can impact a variety of transactions, such as certain compensation, loans or leases between a referring dentist and a hospital, to name just a few examples. The Stark Law prohibits a dentist from making referrals for certain “[designated health services](#)” (DHS)<sup>1</sup> payable by Medicare to an entity with which the dentist, or an immediate family member, has a financial relationship (ownership, investment, or compensation), unless all of the requirements of an applicable exception are satisfied. The Stark Law also prohibits the entity providing the designated

<sup>1</sup> The following items or services are DHS:

1. Clinical laboratory services defined by Code List [https://www.cms.gov/Medicare/Fraud-andAbuse/PhysicianSelfReferral/List\\_of\\_Codes](https://www.cms.gov/Medicare/Fraud-andAbuse/PhysicianSelfReferral/List_of_Codes)
2. Physical therapy services defined by Code List [https://www.cms.gov/Medicare/Fraud-andAbuse/PhysicianSelfReferral/List\\_of\\_Codes](https://www.cms.gov/Medicare/Fraud-andAbuse/PhysicianSelfReferral/List_of_Codes)
3. Occupational therapy services defined by Code List [https://www.cms.gov/Medicare/Fraud-andAbuse/PhysicianSelfReferral/List\\_of\\_Codes](https://www.cms.gov/Medicare/Fraud-andAbuse/PhysicianSelfReferral/List_of_Codes)
4. Outpatient speech-language pathology services defined by Code List [https://www.cms.gov/Medicare/Fraud-andAbuse/PhysicianSelfReferral/List\\_of\\_Codes](https://www.cms.gov/Medicare/Fraud-andAbuse/PhysicianSelfReferral/List_of_Codes)
5. Radiology and certain other imaging services defined by Code List [https://www.cms.gov/Medicare/Fraud-andAbuse/PhysicianSelfReferral/List\\_of\\_Codes](https://www.cms.gov/Medicare/Fraud-andAbuse/PhysicianSelfReferral/List_of_Codes)
6. Radiation therapy services and supplies defined by Code List [https://www.cms.gov/Medicare/Fraud-andAbuse/PhysicianSelfReferral/List\\_of\\_Codes](https://www.cms.gov/Medicare/Fraud-andAbuse/PhysicianSelfReferral/List_of_Codes)
7. Durable medical equipment and supplies
8. Parenteral and enteral nutrients, equipment, and supplies
9. Prosthetics, orthotics, and prosthetic devices and supplies
10. Home health services
11. Outpatient prescription drugs
12. Inpatient and outpatient hospital services

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health service from filing claims with Medicare (or billing another individual, entity, or third party payer) for designated health services furnished pursuant to a prohibited referral.

The [Stark Law exceptions](#) are defined by regulation.

## Anti-Kickback Statute

Under the AKS, it can be a criminal offense to knowingly and willfully offer, pay, solicit or receive remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. The AKS definition of remuneration includes anything of value, whether transferred directly or indirectly, overtly or covertly, in cash or in kind. HHS has promulgated [safe harbor regulations](#) that define practices that are not subject to the AKS because they would be unlikely to result in fraud or abuse.

Resources:

- CMS, [Blanket Waivers of Section 1877\(g\) of the Social Security Act Due to Declaration of COVID-19 Outbreak in the United States as a National Emergency](#), Effective March 1, 2020
- CMS, [COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers](#) Updated September 29, 2020
- OIG, [OIG Policy Statement Regarding Application of Certain Administrative Enforcement Authorities due to Declaration of Coronavirus Disease 2019 \(COVID-19\) Outbreak in the United States as a National Emergency](#), April 3, 2020
- OIG, [FAQs – Application of OIG’s Administrative Enforcement Authorities to Arrangements Directly Connected to the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency](#)
- OIG, [A Roadmap for New Physicians: Fraud & Abuse Laws](#)

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