

HHS OIG Issues Policy Statement Regarding Temporary Federal Anti-Kickback Statute Waivers in Wake of COVID-19

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The U.S. Department of Health and Human Services Office of Inspector General (OIG) has issued a Policy Statement declaring that it will not impose administrative sanctions under the Federal Anti-Kickback Statute for certain remuneration related to COVID-19 covered by **certain** of the same blanket waivers of the Stark Law previously issued by CMS [insert hyperlink to our April 2 Alert] (Policy Statement), but not all of those waivers.

Keep in mind that the remuneration and referrals described in the Stark Law blanket waivers must be solely related to COVID-19 Purposes and thus, the OIG will take the same position with respect to the Policy Statement.

CMS previously defined “COVID-19 Purposes” to mean:

- 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 health care practitioners and professionals to furnish medically necessary patient care services, including services not related to the diagnosis and treatment of COVID-19, in response to COVID-19;
- Ensuring the ability of health care providers to address patient and community needs due to COVID-19;
- Expanding the capacity of health care providers to address patient and community needs due to COVID-19;
- Shifting the diagnosis and care of patients to appropriate alternative settings due to COVID-19; or
- Addressing medical practice or business interruption due to COVID-19 in order to maintain the availability of medical care and related services for patients and the community.

The certain waivers that are covered by the OIG’s Policy Statement are as follows:

1. **Personal Services:** Remuneration from an entity to a physician (or the immediate family member of the physician) that is above or below the fair market value for services personally performed by the physician (or the immediate family member of the physician) to the entity.

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1. An example would be a hospital paying physicians above their previously contracted rate for furnishing professional services for COVID-19 patients in particularly hazardous or challenging environments.
2. **Space and Equipment Rental:** Rental charges paid by an entity to a physician (or the immediate family member of the physician) that are **below** fair market value for the entity's lease of office space or equipment from the physician (or the immediate family member of the physician). Also, rental charges paid by a physician (or an immediate family member of a physician) to an entity that are **below** fair market value for the physician's (or immediate family member's) lease of office space or equipment from the entity.
 1. One example would be a hospital renting office space or equipment from an independent physician practice at below fair market value or at no charge to accommodate patient surge.
 2. Another example would be a hospital's employed physicians using the medical office space and supplies of independent physicians in order to treat patients who are not suspected of exposure to COVID-19 away from their usual medical office space on the campus of the hospital in order to isolate patients suspected of COVID-19 exposure.
 3. A third example would be a hospital providing free use of medical office space on its campus to allow physicians to provide timely and convenient services to patients who come to the hospital, but do not need inpatient care.
 4. A fourth example would be an entity providing free telehealth equipment to a physician practice to facilitate telehealth visits for patients who are observing social distancing or in isolation or quarantine.
3. **Fair Market Value:** Remuneration from an entity to a physician (or the immediate family member of the physician) that is **below** fair market value for items or services purchased by the entity from the physician (or the immediate family member of the physician). Also, remuneration from a physician (or an immediate family member of a physician) to an entity that is **below** fair market value for the use of the entity's premises or for items or services purchased by the physician (or the immediate family member of the physician) from the entity.
 1. One example would be a hospital or home health agency purchasing items or supplies from a physician practice at below fair market value or receiving such items or supplies at no charge.
 2. Another example would be an entity selling personal protective equipment to a physician, or permitting the physician to use space in a tent or other makeshift location, at below fair market value (or providing the items or permitting the use of the premises at no charge).
4. **Medical Staff Incidental Benefits:** Remuneration from a hospital to a physician in the form of medical staff incidental benefits that exceeds the limit set forth in 42 CFR 411.357(m)(5) (currently \$36).
 1. An example would be a hospital providing meals, comfort items (for example, a change of clothing), or onsite childcare with a value greater than \$36 per instance to medical staff

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physicians who spend long hours at the hospital during the declared national emergency.

5. **Nonmonetary Compensation**: Remuneration from an entity to a physician (or the immediate family member of a physician) in the form of nonmonetary compensation that exceeds the limit set forth in 42 CFR 411.357(k)(1) (currently \$423).
 1. One example would be a hospital sending a hospital employee to an independent physician practice to assist with staff training on COVID-19, intake and treatment of patients most appropriately seen in a physician office, and care coordination between the hospital and the practice.
 2. Another example would be an entity providing continuing medical education related to the COVID-19 outbreak, supplies, food, or other grocery items, isolation-related needs (for example, hotel rooms and meals), childcare, or transportation.
6. **Below Market Rate Loans**: Remuneration from an entity to a physician (or the immediate family member of a physician) resulting from a loan to the physician (or the immediate family member of the physician): (i) with an interest rate **below** fair market value or (ii) on terms that are unavailable from a lender that is not a recipient of the physician's referrals or business generated by the physician. Also, remuneration from a physician (or the immediate family member of a physician) to an entity resulting from a loan to the entity: (a) with an interest rate **below** fair market value or (ii) on terms that are unavailable from a lender that is not in a position to generate business for the physician (or the immediate family member of the physician).
 1. One example would be a hospital lending money to a physician practice that provides exclusive anesthesia services at the hospital to offset lost income resulting from the cancellation of elective surgeries to ensure capacity for COVID-19 needs or covering a physician's 15 percent contribution for electronic health records (EHR) items and services in order to continue the physician's access to patient records and ongoing EHR technology support services.
 2. Another example would be a physician owner of a hospital lending money to the hospital to assist with operating expenses of the hospital, including staff overtime compensation, related to the COVID-19 outbreak.

As the Stark Law only applies to self-referrals made by practitioners, and therefore, the blanket waivers of the Stark Law only apply to certain relationships that involve physicians, the Policy Statement for the Federal Anti-Kickback Statute will only waive conduct relating to certain relationships that involve physicians despite the broader scope of the Federal Anti-Kickback Statute.

Somewhat curiously, the Policy Statement only applies to conduct occurring on or after April 3, 2020 even though the Stark Law blanket waivers were effective as to conduct commencing on March 1, 2020.

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The OIG also states that the Policy Statement will terminate on the same date as the date that the Stark Law blanket waivers terminate. As a reminder, that date will be the date that the declaration of the national emergency as a result of the COVID-19 pandemic is no longer in effect.

It is important to remember that the Policy Statement does not waive the provisions of any applicable state anti-kickback laws as the OIG does not have the authority to waive state laws. Care should also be taken to ensure that any arrangements that are entered into utilizing any of the Stark Law blanket waivers (and, as a result of the Policy Statement, Federal Anti-Kickback Statute waivers) should clearly sunset or terminate when the national emergency declaration is terminated.

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