



COVID-19 Update: HHS issues 18 blanket waivers of enforcement of Stark law

March 31, 2020

4/7/2020 Update: The Office of Inspector General (OIG) issued a [policy statement](#) on April 3, 2020, announcing that it will not impose administrative sanctions relating to the commission of acts described in the federal Anti-Kickback Statute, with respect to remuneration that is covered in the first 11 Stark law blanket waivers.

On March 30, 2020, following President Trump's declaration of a national emergency due to the COVID-19 (coronavirus) pandemic, the Secretary of Health and Human Services (Secretary) issued [blanket waivers](#) of enforcement of the Stark law under his 1135 waiver authority. These waivers provide vital flexibility for physicians and providers in the fight against COVID-19. The waivers are effective March 1, 2020 and may be used without notifying CMS.

These blanket waivers mean that, absent any determination of fraud or abuse, if all conditions of a blanket waiver are met, CMS will pay claims for designated health services that would otherwise violate the Stark law.

Physicians and providers wishing to rely on any of these blanket waivers should ensure that all conditions of a waiver are satisfied and that documentation supports and reflects such reliance.

When do the Stark law blanket waivers apply?

The blanket waivers apply only to financial relationships and referrals that are related to the COVID-19 outbreak in the United States. The remuneration and referrals described in the blanket waivers must be solely related to COVID-19 Purposes, which

means:

- 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 the COVID-19 outbreak in the United States;
- Ensuring the ability of health care providers to address patient and community needs due to the COVID-19 outbreak in the United States;
- Expanding the capacity of health care 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.

What are the Stark law blanket waivers?

The Secretary has waived sanctions that would otherwise apply in a number of situations likely to arise during the COVID-19 pandemic, including payment for physician services that is above or below fair market value (FMV), rent paid by physicians below FMV, failure to meet writing requirements and others. A complete list of the available waivers is below.

Note that where indicated by *, the waiver applies to payments made to / by a physician or an immediate family member of a physician.

Waiver	Description of waiver
Services performed by a physician	Remuneration from an entity to a physician* that is above or below FMV for services personally performed by the physician* to the entity.
Office rental (DHS entity is lessee)	Rental charges paid by an entity to a physician* that are below FMV for the entity's lease of office space from the physician*.
Equipment rental (DHS entity is lessee)	Rental charges paid by an entity to a physician* that are below FMV for the entity's lease of equipment from a physician.
Items/services purchased from a physician	Remuneration from an entity to a physician* that is below FMV for items or services purchased by the entity from the physician.
Office rental (physician is lessee)	Rental charges paid by a physician* to an entity that are below FMV for the physician's* lease of office space from the entity.
Equipment rental (physician is lessee)	Rental charges paid by a physician* to an entity that are below FMV for the physician's* lease of equipment from the entity.
Use of a DHS entity's premises or purchase of items/services from entity	Remuneration from a physician* to an entity that is below FMV for the use of the entity's premises or for items or services purchased by the physician* from the entity.
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 per occurrence for the year 2020].
Nonmonetary compensation	Remuneration from an entity to a physician* in the form of nonmonetary compensation that exceeds the limit set forth in 42 CFR 411.357(k)(1)[currently \$423 for the year 2020].
Loan to a physician	Remuneration from an entity to a physician* resulting from a loan to the physician: (1) with an interest rate below FMV or (2) on terms that are unavailable from a lender that

Waiver	Description of waiver
	is not a recipient of the physician's referrals or business generated by the physician*.
Loan to DHS entity	Remuneration from a physician to an entity resulting from a loan to the entity: (1) with an interest rate below FMV or (2) on terms that are unavailable from a lender that is not in a position to generate business for the physician.
Referrals by physician owner of a hospital	The referral by a physician owner of a hospital that temporarily expands its facility capacity above the number of operating rooms, procedure rooms and beds otherwise permitted under the Stark regulations.
Referrals by physician owner of hospitals that recently converted from a physician-owned ASC	Referrals by a physician owner of a hospital that converted from a physician-owned ambulatory surgical center to a hospital on or after March 1, 2020 if specified conditions are met.
Referral to HHA by physician owner	The referral by a physician of a Medicare beneficiary for the provision of designated health services to a home health agency: (1) that does not qualify as a "rural provider" (as defined in the Stark regulations) and (2) in which the physician* has an ownership or investment interest.
Referrals by group practice physician that fail building location tests	The referral by a physician in a group practice for medically necessary designated health services furnished by the group practice in a location that does not qualify as a "same building" or "centralized building" as those terms are defined in the Stark regulations.
Referrals by group practice physicians to patients in homes	The referral by a physician in a group practice for medically necessary designated health services furnished by the group practice to a patient in his or her private home, an assisted living facility or independent living facility where the referring physician's principal medical practice does not consist of treating patients in their private homes.
Referral by physicians to immediate family member-owned entity if patients reside in rural areas	The referral by a physician to an entity with which the physician's immediate family member has a financial relationship if the patient who is referred resides in a rural area.
Lack of writing/signature	Referrals by a physician to an entity with whom the physician* has a compensation arrangement that does not satisfy the writing or signature requirement(s) of an applicable exception but satisfies each other requirement of the applicable exception, unless such requirement is waived under one or more of the blanket waivers set forth above.

Examples of when blanket waivers may apply

The Secretary provided the following non-exhaustive list of examples of remuneration, referrals or conduct that may fall within the scope of the blanket waivers. Unless the blanket waiver expressly applies only to a specific type of entity, examples indicating a hospital also apply to any other type of entity furnishing designated health services.

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 FMV or at no charge.
A hospital's employed physicians use 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.

A hospital or home health agency purchases items or supplies from a physician practice at below FMV or receives such items or supplies at no charge.
A hospital provides 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.
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.
An entity sells personal protective equipment to a physician, or permits the physician to use space in a tent or other makeshift location, at below FMV or at no charge.
A hospital sends 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.
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.
An entity provides nonmonetary compensation to a physician or an immediate family member of a physician in excess of the \$423 per year limit (per physician or immediate family member), such as continuing medical education related to the COVID-19 outbreak in the United States, supplies, food, or other grocery items, isolation-related needs (for example, hotel rooms and meals), child care or transportation.
A hospital lends 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 covers 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.
A physician owner of a hospital lends money to the hospital to assist with operating expenses of the hospital, including staff overtime compensation, related to the COVID-19 outbreak in the United States.
With state approval (if required), a physician-owned hospital temporarily converts observation beds to inpatient beds or otherwise increases its inpatient bed count to accommodate patient surge during the COVID-19 outbreak in the United States.
Consistent with its state's emergency preparedness or pandemic plan, a physician-owned ambulatory surgical center enrolls as a Medicare-participating hospital, even if it is unable to satisfy the requirements that would otherwise apply, in order to provide medically necessary care to patients during the COVID-19 outbreak in the United States.
A physician refers a Medicare beneficiary to a home health agency owned by the immediate family member of the physician because there are no other home health agencies with capacity to provide medically necessary home health services to the beneficiary during the COVID-19 outbreak in the United States.
A group practice furnishes medically necessary magnetic resonance imaging (MRI) or computed tomography (CT) services in a mobile vehicle, van or trailer in the parking lot of the group practice's office to Medicare beneficiaries who would normally receive such services at a hospital, but should not go to the hospital due to concerns about the spread of the COVID-19 outbreak in the United States.
A physician in a group practice whose principal medical practice is office-based orders radiology services that are furnished by the group practice to a Medicare beneficiary who is isolated or observing social distancing in the beneficiary's home.
A physician refers a Medicare beneficiary who resides in a rural area for physical therapy furnished by the medical practice that is owned by the physician's spouse and located within one mile of the beneficiary's residence.
A compensation arrangement that commences prior to the required documentation of the arrangement in writing and the signatures of the parties, but that satisfies all other requirements of the applicable exception, for example— <ul style="list-style-type: none"> • A physician provides call coverage services to a hospital before the arrangement is documented and signed

- by the parties;
- A physician with in-office surgical capability delivers masks and gloves to the hospital before the purchase arrangement is documented and signed by the parties
 - A physician establishes an office in a medical office building owned by the hospital and begins treating patients who present at the hospital for health care services but do not need hospital-level care before the lease arrangement is documented and signed by the parties;
 - The daughter of a physician begins working as the hospital's paid COVID-19 outbreak coordinator before the arrangement is documented and signed by the parties.

Individual waivers

If a health care provider has a situation related to the COVID-19 pandemic that falls within the scope of the Stark law but does not appear to fall within any of the blanket waivers set forth above, individual waivers of sanctions under the Stark law and regulation may be granted upon request. The process for requesting an individual waiver is included on the CMS [website](#).

Documentation/recordkeeping

The Secretary emphasizes that although no permission or notice to CMS is required to utilize a blanket waiver, parties utilizing the blanket waivers must make records relating to the use of the blanket waivers available to the Secretary upon request and encourages parties to develop and maintain records in a timely manner. Although the blanket waivers do not require any specific records or documentation, parties may want to maintain records verifying the applicable COVID-19 purpose, and any other documentation about the arrangement, including supporting documentation indicating why the blanket waiver was utilized and how the arrangement qualified for such waiver.

Authors
