

CMS Issues Temporary Stark Law Waivers in the Wake of COVID-19

Glenn P. Prives

Greenbaum, Rowe, Smith & Davis LLP Client Alert

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In the wake of the COVID-19 pandemic, the Centers for Medicare and Medicaid Services (CMS) have issued several blanket waivers of certain provisions of the Stark Law. The waivers are retroactive to March 1, 2020, and only apply to the geographic area covered by the declaration of the national emergency. These temporary measures will last only for as long as the declaration of the national emergency as a result of the COVID-19 pandemic remains in effect. As always, these actions must be reconciled with any applicable state self-referral laws as CMS does not have the authority to waive state laws.

Providers should take care to ensure that any arrangements that they enter into utilizing any of the above waivers should clearly sunset or terminate when the national emergency declaration is terminated.

As a general matter, any remuneration described in the blanket waivers must be directly between the entity and: (i) the physician or the physician organization in whose shoes the physician stands under 42 CFR 411.354(c) or (ii) the immediate family member of the physician. Further, the remuneration and referrals described in the blanket waivers must be solely related to COVID-19 Purposes.

CMS has 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.

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The waivers are set forth below. In some instances, the waiver is limited to paying below fair market value for services or items. Many exceptions to the Stark Law require remuneration to be fair market value and thus, depending on the exception below, paying above fair market value in some instances may not be covered by a waiver.

Further, CMS has provided examples of the applicability of the waivers.

Personal Services Exception: 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. 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.

Space and Equipment Rental Exceptions: 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. 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. 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. 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. 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.

Fair Market Value Exception: 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. 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. 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).

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

Nonmonetary Compensation Exception: 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). 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. 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.

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). 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. 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.

Exception to Physician Ownership 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 for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of March 23, 2010, but did have a provider agreement in effect on December 31, 2010, the effective date of such provider agreement) without prior application and approval of the expansion of facility capacity as required under section 1877(i)(1)(B) and (i)(3) of the Social Security Act (Act) and 42 CFR 411.362(b)(2) and (c). This waiver in particular must be reconciled with applicable state law relating to licensure of hospitals. Also, 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, provided that: (i) the hospital does not satisfy one or more of the requirements of section 1877(i)(1)(A) through (E) of the Act; (ii) the hospital enrolled in Medicare as a hospital during the period of the declared national

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emergency; (iii) the hospital meets the Medicare conditions of participation and other requirements not waived by CMS during the period of the declared national emergency; and (iv) the hospital's Medicare enrollment is not inconsistent with the emergency preparedness or pandemic plan of the state in which it is located. One example would be a physician-owned hospital temporarily converting observation beds to inpatient beds or otherwise increasing its inpatient bed count to accommodate patient surge during the COVID-19 outbreak. Another example would be a physician-owned ambulatory surgical center enrolling as a Medicare-participating hospital, even if it is unable to satisfy the requirements of section 1877(i)(1) of the Act, in order to provide medically necessary care to patients during the COVID-19 outbreak.

Home Health Agency Ownership: The referral by a physician of a Medicare beneficiary for the provision of designated health services to a home health agency: (i) that does not qualify as a rural provider under 42 CFR 411.356(c)(1) and (ii) in which the physician (or an immediate family member of the physician) has an ownership or investment interest. An example would be a physician referring 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.

Group Practice Exceptions: 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" for purposes of the In-Office Ancillary Services Exception. Also, 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. One example would be a group practice that meets the requirements of 42 CFR 411.352 furnishing medically necessary MRI or 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 COVID-19. Another example would be a physician in a group practice whose principal medical practice is office-based ordering 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, provided that the group practice satisfies all of the requirements of 42 CFR 411.352.

Rural Area Exception: 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. An example would be a physician referring 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.

Exception to Writing and Signature Requirements: Referrals by a physician to an entity with whom the physician (or an immediate family member of 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

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blanket waivers set forth above. One example would be a physician providing call coverage services to a hospital before the arrangement is documented and signed by the parties. Another example would be a physician with in-office surgical capability delivering masks and gloves to the hospital before the purchase arrangement is documented and signed by the parties. A third example would be a physician establishing an office in a medical office building owned by the hospital and beginning to treat 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. A fourth example would be the daughter of a physician beginning working as the hospital's paid COVID-19 outbreak coordinator before the arrangement is documented and signed by the parties.

Please contact the author of this Alert, **Glenn P. Prives** gprives@greenbaumlaw.com | 973.577.1776 with questions or to discuss your individual circumstances. Mr. Prives is a partner in the firm's **Healthcare Department**.