



Secretary Azar Announces Blanket Waivers of Certain Stark Law Prohibitions

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On March 30, 2020, Health and Human Services Secretary Alex M. Azar II announced nationwide COVID-19 "blanket waivers" of certain requirements of the Physician Self-Referral Law (better known as the Stark Law).

In the wake of the national emergency arising from the COVID-19 outbreak, the blanket waivers, under prescribed circumstances, will exempt certain financial arrangements from the Stark Law's referral prohibitions and will allow the Centers for Medicare and Medicaid Services (CMS) to pay claims for related services. When compliance with the Stark Law is not possible due to the COVID-19 pandemic, the waivers are intended to allow hospitals and other Medicare providers to enter into agreements with physicians and physician organizations (or with family members of such physicians) without risk of the normal sanctions and payment bars arising from a violation of the Stark Law, absent the government's determination of fraud or abuse.

The blanket waivers will protect only specific financial relationships, remuneration and referrals for "COVID-19 Purposes," a broadly defined term, including:

- Diagnosis or medically necessary treatment of COVID-19 for any person, whether or not 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 and expanding the ability and 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 to maintain availability of medical care and related services for patients and the community.

When an arrangement is made for COVID-19 Purposes, the blanket waivers allow payment of claims

and preclude sanctions in 18 enumerated circumstances described in the Secretary's announcement. For example, the blanket waivers will protect remuneration from an entity to a physician or family member at rates above or below fair market value for services personally performed by the physician or family member for the entity. The waivers also generally shield office or equipment rental charges paid between an entity and a physician or family member at rates below fair market value. The waivers shelter arrangements in which physicians pay entities less than fair market value for premises, items or services. Also protected is remuneration from a hospital to a physician in the form of medical staff incidental benefits that exceed otherwise applicable regulatory limits. The waivers will guard arrangements involving entity loans to physicians with below market rates or terms unavailable from other lenders.

The waivers also extend protection for a group practice physician's referral for medically necessary designated health services furnished by the group practice at a location that does not qualify as the "same building" or a "centralized building" under the Stark Law's in-office ancillary services exception. The waivers offer further protection for referrals by physician-owners of hospitals temporarily expanded under specific statutory provisions, as well as those converted to hospitals under specified terms.

Secretary Azar's blanket waivers protect physician referrals of Medicare beneficiaries for designated health services to a home health agency that does not qualify as a rural provider in which the physician or family member has an ownership or investment interest. The blanket waivers guard physician referrals to an entity with which the physician's immediate family member has a financial relationship if the referred patient resides in a rural area.

The waivers shield group practice physician referrals for medically necessary designated health services furnished by the group practice to a patient in a private home, 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.

The waivers will safeguard referrals by a physician to an entity with whom the physician or family member 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.

The Secretary's announcement provides the following examples of remuneration, referrals or conduct that would likely be permitted by the blanket waivers:

- A hospital pays independent physicians above their contracted rate for services to COVID-19 patients in particularly hazardous or challenging environments;
- Physician practices rent office space to hospitals for less than fair market value or free of charge to accommodate a COVID-19 patient surge;
- Medical office space and supplies are offered by or to health care systems for free or reduced charges to facilitate isolation of patients suspected of COVID-19 exposure;
- Hospitals purchase or sell items/supplies from or to physician practices for free or at a price under fair market value to facilitate medically necessary care for patients affected or displaced by COVID-

19;

- Hospitals exceed normal limits on non-monetary compensation to physicians or family members to cover costs of isolation-related needs such as food, grocery items, hotel rooms, meals, childcare and transportation;
- An independent anesthesia practice borrows money from the health care system to which it provides exclusive anesthesia services to offset lost income from cancellation of elective surgeries, such that it remains in position to render services for COVID-19 needs;
- A physician refers a Medicare beneficiary to a physical therapy practice in which the physician has a financial interest, where such beneficiary resides in a rural area;
- A physician refers a Medicare beneficiary to a home health agency owned by the physician's spouse because there are no other home health agencies with capacity to provide medically necessary home health services to the beneficiary;
- A physician group practice furnishes medically necessary imaging services from a mobile trailer to patients that ordinarily would receive such services from a hospital but for COVID-19 exposure concerns; and
- A COVID-19 care coordinator is hired by a health care provider and begins performing services before the compensation arrangement is documented and/or signed by the parties.

Secretary Azar encourages parties relying on the blanket waivers to develop and maintain records in a timely manner and is requiring that such records be made available to the Secretary upon request. Submission of a request to CMS to rely upon a blanket waiver is not required. The waivers take effect as of March 1, 2020 and will remain in effect until the Secretary's authority to grant waivers for the COVID-19 outbreak expires. Apart from the blanket waivers, providers may still request individual waivers by emailing such requests to 1877CallCenter@cms.hhs.gov.

The above summarizes Secretary Azar's blanket waivers in general terms; the verbatim text of the blanket waivers is accessible [here](#).

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