

HHS Issues Blanket Waivers for Stark Law

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The COVID-19 von Briesen Task Force issued a Legal Update on March 30 regarding the status of waivers of enforcement under the federal Anti-Kickback Statute (AKS) and Physician Self-Referral Prohibitions (Stark). Underscoring the dynamic nature of the government's response to the COVID-19 outbreak, the Secretary of the Department of Health and Human Services released on that same day far-reaching blanket waivers of Stark's requirements. You can view the HHS Secretary's waiver announcement [here](#).

Summary of Waivers

The Stark waivers are blanket waivers and are intended to ensure that (1) sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid, and CHIP programs; and (2) health care providers that furnish such items and services in good faith, but are unable to comply with one or more of the regulatory requirements that are subject to the waivers due to the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent the government's determination of fraud or abuse.

As we anticipated in our March 30 update, the Stark waivers focus particular attention on the fair market value requirements found in many of the Stark exceptions. The waivers include the following circumstances where compensation might be above or below fair market value:

- Remuneration from an entity to a physician or immediate family member.
- Rental charges for office space or equipment.
- Remuneration for items or services.
- Medical staff incidental benefits.
- Remuneration in the form of nonmonetary compensation.
- Loan provisions with interest rates below fair market value or that are otherwise unavailable from a lender that is not a generator or recipient of the physician's referrals or other business generated.

Moreover, the Stark waivers also address a number of other situations not directly tied to fair market value considerations. These include compensation arrangements that commence prior to documentation of the arrangement in writing and execution by the parties, but which satisfy all other requirements of the applicable exception; waivers of certain requirements relating to referrals to home health agencies in which the physician or an immediate family member has an ownership or investment interest, but which does not qualify as a rural provider; and referrals in a group practice in a location that does not qualify as a "same building" or "centralized building" under the applicable group practice rules.

Finally, the HHS Secretary's waiver declaration includes over twenty examples covering a wide variety of scenarios, including but not limited to:

- Examples specifically pertaining to compensation arrangements that do not satisfy the writing or signature requirements of the applicable exception, such as call coverage arrangements, a physician's delivery of masks and gloves before purchase order documentation is finalized, and a physician who establishes an office in a hospital MOB and begins to provide care prior to finalizing and signing a lease.
- Payments to physicians above previously-contracted rates.
- Rental of office space or equipment or purchases of supplies from physicians to accommodate patient surge.
- Provision of free or below-FMV use of medical office space, telehealth equipment, personal protective equipment, meals, or child care.
- Hospital provision of personnel to assist with training, intake, treatment or care coordination.

Providers who find themselves unable to comply with specific Stark requirements due to the COVID-19 emergency are encouraged to review these examples when assessing whether their inability to comply would be waived under the Secretary's pronouncement. Note that the Stark exceptions for each of the foregoing financial relationships contain additional detailed requirements that are not subject to the waiver and must continue to be met.

Other Items to Consider

The effect of the waivers is that the Centers for Medicaid and Medicare Services will pay claims for designated health services that would otherwise have violated Stark if not for the provider's qualification for the waiver. The waivers only apply to financial relationships and referrals that are related to the national COVID-19 emergency, and the remuneration and referrals must be related solely to COVID-19 Purposes (as that term is defined in the waiver announcement) in order to qualify for the blanket waivers.

Blanket waivers only apply to the specific circumstances described in the individual blanket waiver and health care providers must satisfy all circumstances and conditions of the waiver in order to rely on that waiver. Although health care providers are not required to submit any specific documentation or notice to HHS prior to relying on a waiver, providers must maintain records documenting their use of and eligibility for the waivers and that documentation must be made available to HHS upon request.

The HHS Secretary's blanket waivers of Stark restrictions apply nationwide effective March 1, 2020. The waivers are subject to revision from time to time as the Secretary and CMS determine necessary but any revisions that terminate or narrow the scope of the waivers will be prospective only. The Secretary may issue additional blanket waivers in the days and weeks to come, with effective dates to be announced at that time.

Finally, note that the Secretary's pronouncement does not include waivers under the AKS or civil monetary penalty laws. The provider community continues to look to the Office of Inspector General for guidance under those laws, as discussed in our March 30 update.

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