

# CLINE WILLIAMS

## WRIGHT JOHNSON & OLDFATHER

### **IT'S A BIRD! IT'S A PLANE! NO, IT'S THE HHS SECRETARY TO THE RESCUE! COVID-19 BLANKET STARK WAIVERS THROW PHYSICIANS A LIFELINE**

HHS Secretary Alex Azar provided welcome -- albeit temporary -- relief on March 30<sup>th</sup> to physicians and those who work with them in issuing blanket Section 1135 waivers concerning the application of the Stark Law and its sanctions. The waivers, which are effective March 1, 2020, will last until termination of the COVID-19 public health emergency.

The Stark Law prohibits physicians from making referrals for certain “designated health services” if a physician (or a physician’s immediate family member) has a financial relationship involving ownership or a compensation relationship with the entity receiving the referral. Unless a statutory or regulatory exception under Stark applies, a referral is prohibited under the law, cannot be billed by or reimbursed to the receiving entity and can also generate False Claims Act liability.

The waivers apply only to financial relationships and referrals related to the COVID-19 outbreak in the United States, only to the circumstances described, and only to direct arrangements between an entity and (1) a physician or the physician’s organization; or (2) the immediate family member of the physician. A given arrangement must meet all of the conditions of waiver for the waiver to apply. Physicians and entities relying upon the blanket waivers must maintain records about their use of the blanket waivers and make those records available to the Secretary upon request.

For the Stark Law blanket waivers to apply, the remuneration and referrals “must be solely related to COVID-19 Purposes.” That phrase is defined very broadly to mean any of the following:

- Diagnosis or medically necessary treatment of COVID-19 for any patient or person whether or not he or she is diagnosed with COVID-19;
- Securing physicians and other health care practitioners and professional services to provide patient care services, including services not related to diagnosis and treatment of COVID-19 or response to the outbreak;
- Ensuring the ability and capacity of health care providers to address patient and community needs due to the outbreak;
- Shifting the diagnosis and care of patients to appropriate alternative settings because of the outbreak; or
- Addressing medical practice or business interruption due to the COVID-19 outbreak to maintain medical care and related services availability.

So, for certain referrals and claims for Medicare, Medicaid, or CHIP items and services furnished in good faith between a physician and a DHS entity, Stark Law sanctions are waived for the following arrangements between a DHS entity and a referring physician (or the immediate family member of the physician):

1. Remuneration above or below fair market value for the services personally performed.
2. Below fair market value rent paid to a physician (or an immediate family member of a physician) for an entity's lease of office space or lease of equipment.
3. Below fair market value payment for items or services purchased from a physician (or an immediate family member of a physician) by an entity.
4. Below fair market value for rental paid by a physician (or an immediate family member of a physician) for the lease of office space or equipment.
5. Below fair market value payment from a physician (or an immediate family member of a physician) to an entity for the use of the entity's premises or for items or services purchased.
6. Incidental medical staff benefits or nonmonetary compensation over the regulatory limits.
7. Below fair market value loans or better than market terms to a physician or to an entity.
8. Physician referrals to a physician's own hospital where the facility temporarily expands capacity without prior application and approval of the expansion of facility capacity as required under the Stark Law.
9. 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 certain circumstances are met.
10. Referrals to home health agencies outside of rural areas where the physician (or an immediate family member of the physician) has an ownership or investment interest.
11. Referrals by group practice physicians for DHS furnished by the group in a location that is not the "same building" or a "centralized building" for purposes of the Stark Law or for designated health services furnished by the group 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.
12. Referrals 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.
13. Referrals by a physician to an entity with which the physician or immediate family member has a compensation arrangement that does not satisfy the writing or signature requirement(s) of an applicable Stark Law exception but otherwise satisfies the other

requirements of an applicable exception, unless the requirement is waived under one or more of the blanket waivers set forth above.

Physicians and those who work with them will want to keep in mind that a Stark Law exception may apply under the circumstances, which may make reliance upon a temporary waiver unnecessary. The blanket waivers are not an invitation to go “hog wild” and may be narrowed by HHS on a prospective basis at a later date.

Even though the waivers are temporary, they may provide the very lifeline a physician or physician practice needs to keep its business afloat. As the COVID-19 public health emergency evolves, CMS and other federal or state agencies continue to release guidance.

Please contact a member of the Cline Williams Health Care Section if you have any questions or would like any assistance.



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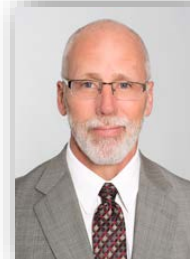
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