

CMS' Blanket Waiver of Stark Law Sanctions During the COVID-19 Outbreak: Opportunities and Limitations

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On Monday, March, 30, 2020, CMS released a blanket waiver (the “Waiver”) of the physician self-referral law under section 1135 of the Social Security Act to enable health care provider responses to the COVID-19 outbreak. Effective retroactively to March 1, 2020, the Waiver broadly eliminates certain key Stark Law requirements for direct financial relationships between entities that provided designated health services (“DHS”) and physicians and physician organizations (or immediate family members of physicians). The Waiver will provide tremendous comfort and flexibility to health care providers attempting to respond rapidly and effectively to the COVID-19 outbreak by lowering many administrative hurdles to and other restrictions on effectuating critical financial relationships. Providers seeking to operate under the Waiver, however, should be mindful of its limitations in proceeding with their COVID-19 response plans.

SCOPE OF THE WAIVER

Relation to COVID-19 Purposes. The Waiver applies exclusively to remuneration and referrals that are “solely related to COVID-19 Purposes.” CMS broadly defines COVID-19 Purposes to include:

- Diagnosis and treatment of COVID-19, regardless of whether the patient is diagnosed with a confirmed case of COVID-19;
- Securing services of physicians and other clinicians in response to the COVID-19 outbreak, including for services not related to the diagnosis and treatment of COVID-19;
- Ensuring and expanding the ability of health care providers to address patient and community needs due to the COVID-19 outbreak;
- Shifting diagnosis and care to appropriate alternative settings due to the COVID-19 outbreak; and
- Addressing medical practice or business interruption due to the COVID-19 outbreak, in order to maintain availability of care and related services.

Types of Non-Compliance. For remuneration provided for COVID-19 Purposes – and “absent the government’s determination of fraud or abuse” – CMS will not impose Stark Law sanctions based on the following types of non-compliance:

- Certain types of remuneration that are **not fair market value**:
 - Remuneration from an entity to a physician for the physician’s personally performed services that is not at fair market value;
 - Remuneration from an entity to a physician for items or services that is below fair market value;
 - Remuneration from a physician to an entity for use of the entity’s premises or for items or services that is below fair market value;
 - Rental charges between a physician and an entity that are below fair market value for a lease of office space or equipment;
- Referrals to an entity with which a physician has a compensation relationship that fails to satisfy the **writing or signature requirements** of an applicable exception, but satisfies all other requirements, unless such requirements are waived by another blanket waiver (for instance, the fair market value requirements specified directly above);
- Certain types of remuneration that **exceed regulatory limits**:
 - Medical staff incidental benefits provided by a hospital to a physician in excess of limits in 42 CFR 411.357(m)(5);
 - Nonmonetary compensation from an entity to a physician in excess of limits in 42 CFR 411.357(k)(1);
- **Non-market loans**, whether from entities to physicians or physicians to entities, with interest rates below fair market value or on terms unavailable from a lender who is not a recipient of business generated by the physician;
- Certain referrals by **physician owners of hospitals**:
 - Referral by a physician owner of a hospital that temporarily expands its facility capacity above licensed capacity on March 23, 2010 without prior application and approval;
 - Referral by a physician owner of a hospital that converted from a physician-owned ambulatory surgery center on or after March 1, 2020, under certain conditions, when the hospital enrolls in Medicare during the public health emergency, meets non-waived Medicare conditions of payment, and its enrollment is not inconsistent with the emergency preparedness or pandemic plan of the state in which it is located;
- Referrals to **home health agencies** in which the referring physician has an ownership or investment interest, and which do not qualify as rural providers;

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- Referrals by physicians in **group practices** for DHS furnished in a location that is not a “same building” or “centralized building”, including in patient homes, assisted living facilities, and independent living facilities; and
 - Referrals to entities with which a physician’s **immediate family member** has a financial relationship if the patient who is referred resides in a rural area.

EXAMPLES OF WAIVER APPLICATION

The Waiver will help to accommodate many of the arrangements into which health care providers have considered entering to address the COVID-19 outbreak. CMS provides specific examples of a variety of such potential applications. Some examples that are likely to provide most comfort to health care providers include:

- Payments to physicians in excess of previously-contracted rates to recognize challenges in furnishing services during the COVID-19 outbreak;
- Rentals of office space or equipment by hospitals to physicians at below fair market value or for free to help accommodate patient surge or promote non-hospital care availability;
- Free telehealth equipment from an entity to a physician practice to facilitate telehealth visits for patients observing social distancing or in isolation or quarantine;
- Provision of personal protective equipment to physicians by entities at below fair market or for free;
- Hospital training and administrative assistance for independent physician practices;
- Hospital assistance to physicians working to treat COVID-19 in the form of child care, meals, comfort items, medical education, supplies or transportation;
- Loans to physicians who have lost income because of cancellation of elective services to ensure continuing capacity;
- Coverage of a physician’s 15% contribution for electronic health records to continue access to patient records and technology support;
- Group practice provision of MRI or CT services in a mobile van; and
- Compensation arrangements that commence prior to required documentation.

WAIVER LIMITATIONS

The Waiver provides broad protection from Stark Law sanctions for many of the types of financial relationships that health care providers may seek to enter in responding to the COVID-19 outbreak. However, the Waiver has several important limitations that providers should keep in mind as they proceed to enter into new financial relationships:

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- While the Waiver removes sanctions for non-compliance with many of the Stark Law's fair market value requirements, and its requirements that certain compensation arrangements be in writing and signed by the parties, it does not affect other key requirements in many exceptions, including that compensation be set in advance, that services or space be specified, or that arrangements be commercially reasonable. CMS' failure to address these requirements could seriously impair the practical usefulness of the Waiver for many important financial relationships. For instance, while it will undoubtedly be helpful to quickly onboarding physicians to be relieved of requirements to obtain a signed written contract, it often takes substantial (and, in the context of the COVID-19 outbreak, unavailable) time to negotiate final compensation terms, which could still leave important arrangements in potentially sanctionable non-compliance with the Stark Law. Similarly, the removal of fair market value requirements will be extremely useful in enabling rapid and effective formation of important financial relationships, it may still be difficult for providers to gauge and comply with requirements for commercial reasonableness, particularly in the current unprecedented circumstances.
 - The Waiver applies only to direct financial relationships, and not to indirect compensation arrangements. Therefore, a relationship that meets the definition of an indirect compensation arrangement – for instance, an arrangement between a parent health system that operates hospitals and a physician that provides for compensation that varies with the volume or value of referrals by the physician to one of the hospitals – would not appear to qualify for any relief from the requirements of the exception for indirect compensation arrangements.
 - CMS explicitly encourages parties “to develop and maintain records in a timely manner as a best practice” and requires that “[p]arties utilizing the blanket waivers must make records relating to the use of the blanket waivers available to the Secretary upon request.” Therefore, while the waivers certainly provide substantial new flexibility, they should not be read to wholly relieve the prudent health care provider of the need to carefully document efforts.
 - The Waiver only protects remuneration and referrals that are “solely related to the COVID-19 Purposes.” The effective introduction of an intent element to the Stark Law – which is, under normal circumstances, a strict liability statute – may require a novel analytical approach to considering arrangements that potentially implicate the Stark Law. Health care providers seeking to operate under the Waiver should carefully consider – and, where possible, document – their purposes in entering into arrangements, particularly where there may be an appearance of any non-COVID-19-related objectives.
 - Related, the Waiver only applies to Stark Law sanctions, and not to sanctions under the federal Anti-Kickback Statute, although the OIG released a statement earlier today promising to “carefully consider the context and intent of the parties when assessing whether to proceed with any enforcement action” related to arrangements developed as part of a COVID-19 response. See <https://oig.hhs.gov/coronavirus/letter-grimm-03302020.asp>.
 - The Waiver applies only “absent the government's determination of fraud or abuse.” The Waiver provides no detail as to when such a determination would apply, but with this caveat the government retains the ability to sanction arrangements that it finds problematic.
 - The Waiver waives “the sanctions under section 1877(g) of the Act and regulations thereunder”, but does not waive the Stark Law itself. The practical import of this distinction is not clear, but the terms of the Waiver would leave a provider that entered into an unexcepted

financial relationship covered by the Waiver in violation of the Stark Law, even if not subject to Stark Law sanctions. It is possible that, on this basis, an aggressive government enforcer could pursue, for instance, a False Claims Act claim based on the underlying non-compliance.

Health care providers can and must proceed with their efforts to respond effectively to the COVID-19 outbreak, and the Waiver will provide useful flexibility for these efforts. Nevertheless, we encourage providers to be mindful of the Waiver's potential limitations and their implications. We are available to help with your questions about the Waiver and how it can facilitate your COVID-19 response efforts.

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