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CMS ISSUES BLANKET WAIVERS OF THE STARK LAW IN RESPONSE TO THE COVID-19 PANDEMIC

by Matt Lipton and Rachel Freeman
April 2, 2020

Following the declaration of a national emergency as a result of the COVID-19 pandemic, on March 30, 2020 (and effective retroactively to March 1, 2020) the Centers for Medicare and Medicaid Services (CMS) issued a series of blanket waivers aimed at creating flexibility for healthcare providers in their fight against COVID-19. One of these blanket waivers relates to the application of Section 1877 of the Social Security Act, commonly referred to as the "Stark Law", to arrangements with COVID-19-related purposes (the Stark Blanket Waiver).

Generally speaking, the Stark Law prohibits a physician from making referrals for certain designated health services (DHS) to an entity with which the physician has a financial relationship, and the entity receiving the referral is prohibited from billing for the DHS, unless the financial relationship between the physician and the entity meets an exception. Under the Stark Blanket Waiver, the referral prohibitions and associated sanctions may be waived, as long as all conditions of the waiver are met. These conditions are briefly discussed below.

First, the Stark Blanket Waiver only applies to arrangements that are entered into for a "COVID-19-related purpose", which is defined to mean:

1. The diagnosis or treatment of COVID-19 for any patient;
2. Securing the services of providers to furnish services, including services not related to the diagnosis and treatment of COVID-19;
3. Ensuring the ability of providers to address patient needs in light of the outbreak;
4. Expanding the capacity of providers to address patient needs due to the outbreak;
5. Transitioning the diagnosis and treatment of patients to alternative locations as a result of the outbreak; or
6. Minimizing medical practice interruption caused by the outbreak so as to maintain the availability of medical services for patients.

Second, the Stark Blanket Waiver only applies to certain designated conduct that might otherwise be found to violate the Stark Law. Designated conduct includes:

1. Payments for items or services that are either above or below fair market value;
2. Rent associated with the lease of space or equipment that is below fair market value;
3. Medical staff incidental benefits that exceed the current legal limit ($25);
4. Nonmonetary compensation that exceeds the current legal limit ($300);
5. Loans with interest rates below fair market value or on terms that are unavailable from lenders;
6. Under certain circumstances, the referral by a physician owner of a hospital that temporarily expands without prior application and approval of the expansion;
7. Under certain circumstances, 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;
8. The referral for DHS to a home health agency that does not qualify as a rural provider and in which the physician has an ownership interest;
9. The referral by a physician in a group practice for DHS furnished by the group practice in a location that does not qualify as a "same building" or "centralized building";
10. The referral by a physician in a group practice for DHS furnished by the group practice to patients in their private homes or independent/assisted living facility;

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11. The referral by a physician to an entity with which the physician's immediate family member has a financial relationship if the referred patient lives in a rural area; and
12. Referrals by a physician to an entity with whom the physician has a compensation arrangement that does not satisfy the writing or signature requirement(s) of an applicable exception.

CMS provides a number of examples of scenarios that would meet the requirement of the Stark Blanket Waiver, such as a hospital providing free office space to providers in order to allow them to see and treat patients who come to the hospital but do not need to be admitted, and an entity's provision of free telehealth equipment to a provider to facilitate telehealth visits for patients who are engaged in social distancing and/or who are quarantined/isolated.

While all conditions of the Stark Blanket Waiver must be satisfied, there is no requirement that a provider submit any notice or documentation to CMS prior to relying on the Stark Blanket Waiver. That said, providers who wish to rely on any blanket waiver must make records relating to the use of the blanket waiver available to the Secretary upon request. As such, providers have been specifically encouraged by CMS to maintain such records on a real-time basis in the course of their business.

INDIVIDUAL WAIVER REQUESTS

CMS also offers individual waivers of the Stark law. Individual waivers may be requested via email at 1877CallCenter@cms.hhs.gov and should include the words "Request for 1877(g) Waiver" in the subject line. All requests should include the following minimum information: 1) the name and address of requesting entity, 2) the name, phone number and email address of person designated to represent the entity, 3) CMS Certification Number or Taxpayer Identification Number of the requesting entity; and 4) the nature of request. Unless or until CMS approves an individual waiver request, the requesting party remains subject to the requirements of the Stark Law.

All waivers, including the Stark Blanket Waiver, will remain in effect until the termination of the current public health emergency, the national emergency or 60 days, whichever is later.

Laws, regulations and guidance addressing the COVID-19 pandemic are rapidly evolving and highly fact specific. If you have questions about the application of the Stark Blanket Waiver or other legal issues associated with COVID-19, please contact us.

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