

CMS Issues Blanket Stark Law Waivers to Help Providers Fight COVID-19

April 2, 2020

By **Lori Beam**

On March 30, 2020, the Centers for Medicare and Medicaid Services (CMS) issued 18 nationwide blanket waivers to sanctions under the physician-self referral law known as the Stark Law, providing greater flexibility to hospitals and physicians as they urgently collaborate to deal with the COVID-19 pandemic.

CMS also compiled into one document all CMS waivers granted to non-physician providers to date as part of its COVID-19 Emergency Declaration for Health Providers.

Stark Law Blanket Waivers

The Stark Law prohibits physicians from referring certain designated healthcare services (DHS) covered by Medicare to entities that have a direct or indirect financial relationship with the referring physician or an immediate family member of the referring physician. And it bans DHS entities from billing Medicare for DHS generated by such prohibited physician referrals. Only financial relationships that meet a Stark Law exception are exempt.

The new temporary Stark Law blanket waivers are ***retroactive to March 1, 2020*.** They apply solely to financial arrangements entered into for "COVID-19 Purposes" that also meet all of the elements ***of at least one*** of the 18 new blanket waivers. When applicable, the waivers exempt physicians and DHS providers from the Stark Law's referral and billing bans.

CMS defines "COVID-19 Purposes" to mean –
• Diagnosis or medically necessary treatment of COVID-19 for any patient or individual, whether or not the patient or individual is 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 the COVID-19 outbreak in the United States;
• Ensuring the ability of healthcare providers to address patient and community needs due to the COVID-19 outbreak in the United States;
• Expanding the capacity of healthcare providers to address patient and community needs due to the COVID-19 outbreak in the United States;

• Shifting the diagnosis and care of patients to appropriate alternative settings due to the COVID-19 outbreak in the United States; or
• Addressing medical practice or business interruption due to the COVID-19 outbreak in the United States in order to maintain the availability of medical care and related services for patients and the community.

Technical Requirements

Like the Stark Statute itself, the blanket waivers contain technical requirements that the parties must meet to qualify for exemption. Accordingly, when entering into financial arrangements for COVID-19 Purposes, hospitals and physicians should review the precise wording of the applicable blanket waiver to ensure the arrangement meets the stated requirements.

Also instructive is CMS's long list of examples of how these blanket waivers can be used for COVID-19 Purposes.

Some of the key blanket waivers include:
(1) A DHS entity paying above or below fair market value (FMV) remuneration to a physician for services personally performed by the physician, allowing, for example, paying a physician a higher than previously contracted rate for working in particularly hazardous or challenging environments.
(2) A physician paying below market rent to a DHS entity for the physician's use of space or purchase of items or services from the DHS entity, allowing for example the provision of free personal protective equipment.
(3) Medical staff incidental benefits that exceed the current $36 limit per occurrence, such as meals, changes of clothing or onsite childcare.
(4) Non-monetary compensation to a physician that exceeds the $423 annual limit for things like COVID-19 CME, hotel rooms and food for isolation needs.
(5) Loans to physicians at below FMV interest and non-commercial terms to ensure continued availability of the physician's services to treat COVID-19 patients.
(6) A compensation arrangement that doesn't meet the writing and signature requirements of a Stark regulatory exception but otherwise meets the exception.

Again, to see the precise wording of these waivers and all 18 waivers, go to **CMS's Blanket Waivers of Section 1877(g) document.**

Some cautions:
• The blanket waivers only apply to remuneration directly between the DHS entity and the physician or the physician organization in which the physician stands in the shoes. So, indirect compensation arrangements (as defined by the Stark Law) still need to meet a regulatory exception.
• The blanket waivers apply "absent the government's determination of fraud and abuse," which is another way of conditioning compliance with the blanket waiver on compliance with the Anti-Kickback Statute and other fraud and abuse laws involving bad faith intent.
• CMS says the parties must make records relating to their use of the blanket waivers available to CMS on request. So, the parties should document how the financial relationship is expected to achieve one or more of the COVID-19 purposes and is otherwise reasonable in the emergency COVID-19 circumstances consistent with good faith intent.

Stark Law Case-By-Case Waivers

Hospitals and physicians also can request arrangement-specific waivers from CMS. On March 13, 2020, the Secretary of HHS exercised his emergency authority under Section 1135 of the Social Security Act to waive various Medicare and Medicaid laws and regulations, including a waiver of Stark Law sanctions

under such conditions and circumstances as CMS determines appropriate.
• CMS did not issue any additional guidance on how it will implement this Stark Law waiver for the COVID-19 emergency.
• Last year CMS issued a FAQ explaining its policies and procedures for Section 1135 waivers. If it follows those same rules for COVID-19 pandemic, CMS will grant Stark Law waivers on a case-by-case basis when it determines a waiver will help address healthcare needs necessitated by the emergency. According to the FAQ:

- Hospitals should email their requests for waivers to their CMS regional office at the email address listed for them in the FAQ, providing specific details (in no particular format) concerning the actual or proposed financial relationship between the referring physicians and DHS entity.
- Requests for waivers will receive a response within three days.

Welcome Relief

The CMS blanket Stark Law waivers cover a broad range of arrangements for addressing COVID-19 needs while offering welcome relief to health care providers trying to save lives.

This article is general in nature and does not constitute legal advice. Readers with legal questions should consult the author, Lori Beam (lbeam@sb-kc.com) or any other shareholders in Seigfreid Bingham's Health Law Group, including Mark Thompson, Joseph Hiersteiner, Mark Gilgus, John Neyens, Mark Opara, Heath Hoobing and John Fuchs, or your regular contact at Seigfreid Bingham at 816-421-4460. For more information and updates, visit our **COVID-19 Resources page.**