

Report on Medicare Compliance Volume 29, Number 12. March 30, 2020

Stark Law and Waivers: The Bird's-Eye View

Attorneys at Morgan Lewis briefly described the parameters of the Sec. 1135 waiver, which has been invoked because of the coronavirus public health emergency, for relief under the Stark Law at a March 24 webinar.^[1]

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1135 Waiver: Stark Law

- Included in the Secretary's March 13 1135 Waivers was the following: "Sanctions from section 1877(g) [42 U.S.C. § 1395nn] (relating to limitations on physician referrals) under such conditions and in such circumstances as the Centers for Medicare & Medicaid Services determines appropriate."
- The challenges created by the strict liability nature of the Stark Law are exacerbated by the COVID-19 public health crisis.
- As hospitals and other healthcare providers respond to the crisis, they will inevitably engage physicians for assistance and likely establish "compensation arrangements" as defined by the Stark Law. Most compensation arrangement exceptions include the "writing" requirement.
- Other providers may seek to support certain groups of physicians that are harmed as a result of the crisis, such as the cancelation of elective surgeries.
- The Stark Law waiver is not self-implementing.
- Request for waivers related to COVID-19 will be handled by CMS's central office in Baltimore. Requests can be sent to 1877CallCenter@CMS.hhs.gov. Include the words "Request for 1877(g) Waiver" in the subject line of the email.
 - All requests should include the following information:
 - Name and address of requesting entity
 - Name, phone number and email address of a designated representative
 - CMS Certification Number or Taxpayer Identification Number
 - Nature of the request
- CMS will grant waivers only on request and on a case-by-case basis, based on the details concerning the actual or proposed financial relationship between the referring physician and entity.
- Unless and until a waiver is granted to the requesting parties, compliance with the Stark Law is required.
- Most potential compensation arrangements with physicians can meet an existing Stark Law exception:

- Employment
- Fair Market Value
- Personal Service Arrangements
- Do whatever you can to memorialize the arrangement in writing (e.g., emails) and include the essential terms. Signatures can be obtained 90 days from the date on which the arrangement became noncompliant. 42 C.F.R. § 411.353(g) .
- Physicians may donate their time to tax exempt entities so long as the donation is not solicited or offered in a manner that takes into account the volume or value of referrals between the parties. 42 C.F.R. § 411.357(j) .

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