CMS Issues Blanket Waivers of Sanctions under the Physician Self-Referral Law

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On April 21, CMS issued Explanatory Guidance on the Blanket Waivers available at: https://www.cms.gov/files/document/explanatory-guidance-march-30-2020-blanket-waivers-section1877g-social-security-act.pdf. Among other matters, CMS reiterates that financial relationships or referrals "must satisfy all non-waived requirements of an applicable exception" to avoid the Stark Law's referral and billing prohibitions. CMS also stated it will work with the Department of Justice to address False Claims Act relator suits where parties using the blanket waivers have a good faith belief that financial relationships are covered by a waiver. Refer to the full CMS guidance for further information.

On March 30, 2020, CMS issued blanket waivers of sanctions under the physician self-referral law (Stark) for COVID-19 Purposes. CMS announced that these waivers provide vital flexibility for physicians and providers in the fight against COVID-19. The waivers are effective March 1, 2020, and may be used without notifying CMS. Please contact MercyOne Legal or Integrity and Compliance for assistance if you are planning to take action in reliance on a waiver.

Waivers are to be used if a provider is unable to comply with one or more of the specified requirements of the Stark Law and regulations. Providers utilizing these waivers may still be reimbursed under such programs and will be exempt from sanctions for such noncompliance “absent the government’s determination of fraud or abuse.” Each waiver must be solely related to COVID-19 purposes.

Of the 18 waivers, those expected to be of most likely value to MercyOne are:

- **Personally Performed Services by a Physician**: Remuneration from an entity to a physician (or an immediate family member of a physician) that is above or below the fair market value (“FMV”) for services personally performed by the physician (or the immediate family member of the physician) to the entity;

- **Office Space [or equipment] Rented from a Physician**: Rental charges paid by an entity to a physician (or an immediate family member of a physician) that are below FMV for the entity’s lease of office space from the physician (or the immediate family member of the physician).

- **Office Space [or equipment] Rented to a Physician**: Rental charges paid by a physician (or an immediate family member of a physician) to an entity that are below FMV for the physician’s (or immediate family member’s) lease of office space from the entity;

- **Medical Staff Incidental Benefits**: Remuneration from a hospital to a physician in the form of medical staff incidental benefits that exceeds $36.00 per occurrence in calendar year 2020 (which is the limit set forth in 42CFR 411.357(m)(5));

- **Non-Monetary Compensation**: Remuneration from an entity to a physician (or the immediate family member of a physician) in the form of nonmonetary compensation that exceeds $423 in calendar year 2020 (which is the limit is set forth in 42 CFR 411.357(k)(1));
• **Loans to a Physician:** Remuneration from an entity to a physician (or the immediate family member of a physician) resulting from a loan to the physician (or the immediate family member of the physician): (1) with an interest rate below FMV, or (2) on terms that are unavailable from a lender that is not a recipient of the physician's referrals or business generated by the physician;

• **In-Office Ancillary Services in Home:** The referral by a physician in a group practice for medically necessary designated health services furnished by the group practice to a patient in his or her private home, an assisted living facility, or an independent living facility where the referring physician's principal medical practice does not consist of treating patients in their private homes;

• **Writing Requirement:** Referrals by a physician to an entity with whom the physician (or an immediate family member of the physician) has a compensation arrangement that does not satisfy the writing or signature requirement(s) of an applicable exception but satisfies every other requirement of the applicable exception, unless such requirement is waived under one or more of the Blanket Waivers set forth above.

CMS provided further directions as follows (emphasis added):

*Parties utilizing the blanket waivers must make records relating to the use of the blanket waivers available to the Secretary upon request.* Although the blanket waivers may be used beginning on the effective date set forth in section II.A of this blanket waiver document and do not require the submission of specific documentation or notice to the Secretary or CMS in advance of their use, **CMS encourages parties to develop and maintain records in a timely manner as a best practice.**

Information about the Stark Blanket Waivers and additional Stark waivers is posted at [https://www.cms.gov/Medicare/Fraud-andAbuse/PhysicianSelfReferral/Spotlight](https://www.cms.gov/Medicare/Fraud-andAbuse/PhysicianSelfReferral/Spotlight)

**IMPORTANT:** Please note that unless and until a waiver of sanctions under the physician self-referral law (that is, a waiver of section 1877(g) of the Social Security Act (the Act)) is granted to the requesting party(ies), such party(ies) must comply with section 1877 of the Act and the regulations at 42 C.F.R. § 411.350 et seq.