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CMS Waives Stark Law Limits to Hospital-Physician Arrangements During COVID-19 Pandemic

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On March 30, 2020, CMS opened the way for hospitals to provide additional compensation and/or support to referring physicians during the COVID-19 pandemic by waiving the enforcement penalties under the federal Ethics in Patient Referrals Act (“Stark”). (See <https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf>).

I. Stark Law Prohibitions.

Stark generally prohibits physicians from ordering or referring certain designated health services (“DHS”) payable by Medicare or Medicaid to a hospital or other entity with which the physician (or a member of the physician’s family) has a financial relationship unless the arrangement is structured to fit within a regulatory safe harbor. (42 U.S.C. § 1395nn; 42 C.F.R. § 411.353). Those safe harbors may be difficult to satisfy in the COVID-19 crisis but for the CMS waivers.

II. Stark Law Waivers.

1. **Conditions.** To fit within the CMS waivers: (1) the arrangement with the referring physician may not involve fraud and abuse; (2) the remuneration provided must be directly between the hospital or other DHS entity and the physician or the physician’s organization under 42 C.F.R. § 411.354(c), or the immediate family member of the physician; and (3) the remuneration and referrals must be solely related to COVID-19 Purposes. “COVID-19 Purposes” include, but are not limited to:
 - 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 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.
 - Ensuring the ability of health care providers to address patient and community needs due to the COVID-19 outbreak.
 - Expanding the capacity of health care providers to address patient and community needs due to the COVID-19

outbreak.

- Shifting the diagnosis and care of patients to appropriate alternative settings due to the COVID-19 outbreak.
- 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.

2. **Blanket Waivers.** Assuming the conditions are satisfied, the CMS waivers apply to specified financial arrangements and/or referrals, e.g.:

- Remuneration from a hospital to a physician that is above or below the fair market value for the services provided.
- Rent or payments for space, equipment, or supplies that are above or below fair market value depending on the circumstances.
- Incidental benefits or nonmonetary compensation that exceeds the limits in Stark.
- Loans that are below fair market value or are on terms that are unavailable from other lenders.
- Certain referrals by a physician to entities that the physician owns that might otherwise be precluded under Stark.

3. **Examples of Waived Arrangements.** The CMS guidance contains numerous helpful examples of permissible arrangements assuming the other conditions are satisfied, including but not limited to the following:

- A hospital pays physicians above their previously-contracted rate for furnishing services for COVID-19 patients under hazardous conditions.
- A hospital lends money to a physician practice to offset lost income resulting from the cancellation of elective surgeries to ensure capacity for COVID-19 needs.
- To accommodate patient surge, a hospital rents office space or equipment from a physician practice at below fair market value or at no charge.
- A hospital's employed physicians use the medical office space and supplies of independent physicians to treat patients and avoid the spread of COVID-19.
- A hospital or home health agency purchases items or supplies from a physician practice at below fair market value or receives such items or supplies at no charge.
- A hospital provides free medical office space on its campus to allow physicians to provide services to patients who come to the hospital but do not need inpatient care.
- A hospital provides free telehealth equipment to a physician practice to facilitate telehealth visits for patients who are observing social distancing or in isolation.

- An entity sells personal protective equipment to a physician or permits the physician to use space at below fair market value.
- A hospital sends a hospital employee to an independent physician practice to assist with staff training on COVID-19, intake and treatment of patients most appropriately seen in a physician office, and care coordination between the hospital and the practice.
- A hospital provides meals, hotel rooms, groceries, comfort items, or onsite child care to medical staff physicians responding to COVID-19 cases.
- With any required state approval, a physician-owned hospital temporarily converts observation beds to inpatient beds or otherwise increases its inpatient bed count to accommodate patient surge during the COVID-19 outbreak.
- Consistent with its State's Emergency Preparedness or Pandemic Plan, a physician-owned ambulatory surgical center enrolls as a Medicare-participating hospital to provide medically necessary care to patients during the COVID-19 outbreak.
- A physician refers a Medicare beneficiary to a home health agency owned by the immediate family member of the physician because there are no other home health agencies with capacity to provide medically necessary home health services to the beneficiary during the COVID-19 outbreak in the United States.

Hospitals and providers should review the specific waivers and examples in the CMS guidance to confirm whether a proposed arrangement would fit within the waiver.

III. Additional Limitations. The CMS waivers only apply to Stark law situations and, even then, only if the arrangement does not result in fraud or abuse. Hospitals, physicians and other entities must also consider whether the arrangements violate other state or federal laws, including but not limited to the federal Anti-Kickback Statute. On March 30, the OIG issued a statement affirming that “[f]or any conduct during this emergency that may be subject to OIG administrative enforcement, OIG will carefully consider the context and intent of the parties when assessing whether to proceed with any enforcement action.”

<https://oig.hhs.gov/coronavirus/letter-grimm-03302020.asp>.

We encourage you to visit Holland & Hart's Coronavirus Resource Site, a consolidated informational resource offering practical guidelines and proactive solutions to help companies protect their business interests and their workforce. The dynamic Resource Site is regularly refreshed with new topics and updates as the COVID-19 outbreak and the legal and regulatory responses continue to evolve. Sign up to receive updates and for

upcoming webinars.

For questions regarding this update, please contact:

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