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CMS Stark and OIG Anti-Kickback Act Enforcement Waivers Related to the COVID-19 Pandemic

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The Centers for Medicare and Medicaid Services (CMS) issued sweeping waivers related to compliance with the Ethics in Patient Referral Act (Stark) to assist health care providers in servicing patients during the Coronavirus Disease 2019 (COVID-19) health care emergency. These waivers are designed to assist health care professionals in meeting the need to provide staffing and services to patients. While the waivers are broad in nature, they are specific to the COVID-19 emergency, and accordingly, are not general waivers of the prohibition on physician self-referrals; the waivers excuse certain elements of compliance to meet some of the exceptions. Similarly, the Office of Inspector General (OIG) released a statement of policy that joined with the CMS waivers, announcing that it would not seek enforcement for conduct that meets the conditions of the CMS waivers.

The CMS Blanket waiver was issued pursuant to Section 1135 of the Social Security Act, which authorizes the Secretary of the Department of Health and Human Services to waive or modify certain Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act (HIPAA) of 1996 requirements during a declared public health emergency. Such waivers may be granted to the extent necessary to ensure: (1) sufficient health care items and services are available to meet the needs of individuals in the emergency area enrolled in the Medicare, Medicaid, and CHIP programs; and (2) health care providers that furnish such items and services in good faith, but that are unable to comply with one or more requirements may be reimbursed for such items and services and exempted from sanctions for such noncompliance absent any determination of fraud or abuse.

Importantly, the waivers are limited to the enumerated circumstances set forth in the waiver; the parties taking advantage of the waivers must satisfy all conditions of the blanket waiver. CMS acknowledged that most relationships between physicians and designated health services will already be covered by an existing Stark exception and that such relationships will continue to be covered by the existing exception. The waivers were retroactively put into effect beginning March 1, 2020, and are valid until the expiration of the emergency.

CMS made clear that the waivers are related solely to COVID-19 purposes, which are defined as:

- 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 health care providers to address patient and community needs due to the COVID-19 outbreak in the United States;
- Expanding the capacity of health care 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.

The waivers apply to the following:

1. Remuneration from an entity to a physician (or an immediate family member of a physician) that is above or below the fair market value for services personally performed by the physician (or the immediate family member of the physician) to the entity.
2. Rental charges paid by an entity to a physician (or an immediate family member of a physician) that are below fair market value for the entity's lease of office space from the physician (or the immediate family member of the physician).
3. Rental charges paid by an entity to a physician (or an immediate family member of a physician) that are below fair market value for the entity's lease of equipment from the physician (or the immediate family member of the physician).
4. Remuneration from an entity to a physician (or an immediate family member of a physician) that is below fair market value for items or services purchased by the entity from the physician (or the immediate family member of the physician).
5. Rental charges paid by a physician (or an immediate family member of a physician) to an entity that are below fair market value for the physician's (or immediate family member's) lease of office space from the entity.
6. Rental charges paid by a physician (or an immediate family member of a physician) to an entity that are below fair market value for the physician's (or immediate family member's) lease of equipment from the entity.
7. Remuneration from a physician (or an immediate family member of a physician) to an entity that is below fair market value for the use of the entity's premises or for items or services purchased by the physician (or the immediate family member of the physician) from the entity.
8. Remuneration from a hospital to a physician in the form of medical staff incidental benefits

that exceeds the limit set forth in 42 CFR 411.357(m)(5).

9. Remuneration from an entity to a physician (or the immediate family member of a physician) in the form of non-monetary compensation that exceeds the limit set forth in 42 CFR 411.357(k)(1).

10. 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 fair market value; 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.

11. Remuneration from a physician (or the immediate family member of a physician) to an entity resulting from a loan to the entity: (1) with an interest rate below fair market value; or (2) on terms that are unavailable from a lender that is not in a position to generate business for the physician (or the immediate family member of the physician).

12. The referral by a physician owner of a hospital that temporarily expands its facility capacity above the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of March 23, 2010, but did have a provider agreement in effect on Dec. 31, 2010, the effective date of such provider agreement) without prior application and approval of the expansion of facility capacity as required under section 1877(i)(1)(B) and (i)(3) of the Act and 42 CFR 411.362(b)(2) and (c).

13. 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, provided that: (i) the hospital does not satisfy one or more of the requirements of section 1877(i)(1)(A) through (E) of the Act; (ii) the hospital enrolled in Medicare as a hospital during the period of the public health emergency; (iii) the hospital meets the Medicare conditions of participation and other requirements not waived by CMS during the period of the public health emergency; and (iv) the hospital's Medicare enrollment is not inconsistent with the Emergency Preparedness or Pandemic Plan of the State in which it is located.

14. The referral by a physician of a Medicare beneficiary for the provision of designated health services to a home health agency: (1) that does not qualify as a rural provider under 42 CFR 411.356(c)(1); and (2) in which the physician (or an immediate family member of the physician) has an ownership or investment interest.

15. The referral by a physician in a group practice for medically necessary designated health services furnished by the group practice in a location that does not qualify as a "same building" or "centralized building" for purposes of 42 CFR 411.355(b)(2).

16. 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 independent living facility where the referring physician's principal medical practice does not consist of treating patients in their private homes.

17. The referral by a physician to an entity with which the physician's immediate family member has a financial relationship if the patient who is referred resides in a rural area.

18. 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 each other requirement of the applicable exception, unless such requirement is waived under one or more of the blanket waivers set forth above.

CMS provides examples of the types of activities that fall under the blanket waiver. These primarily relate to retention of a physician to provide services, use of space, and similar issues. Following are some of the examples:

- A hospital pays physicians above their previously contracted rate for furnishing professional services for COVID-19 patients in particularly hazardous or challenging environments.
- To accommodate patient surge, a hospital rents office space or equipment from an independent 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 in order to treat patients who are not suspected of exposure to COVID-19 away from their usual medical office space on the campus of the hospital in order to isolate patients suspected of COVID-19 exposure.
- 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 use of medical office space on its campus to allow physicians to provide timely and convenient services to patients who come to the hospital but do not need inpatient care.
- An entity provides free telehealth equipment to a physician practice to facilitate telehealth visits for patients who are observing social distancing or in isolation or quarantine.
- A hospital lends money to a physician practice that provides exclusive anesthesia services at the hospital to offset lost income resulting from the cancellation of elective surgeries to ensure capacity for COVID-19 needs or covers a physician's 15 percent contribution for electronic health records (EHR) items and services in order to continue the physician's access to patient records and ongoing EHR technology support services.
- A compensation arrangement that commences prior to the required documentation of the arrangement in writing and the signatures of the parties, but that satisfies all other requirements of the applicable exception, for example—
    - A physician provides call coverage services to a hospital before the arrangement is documented and signed by the parties;
    - A physician with in-office surgical capability delivers masks and gloves to the hospital before the purchase arrangement is documented and signed by the parties;

  - A physician establishes an office in a medical office building owned by the hospital and begins treating patients who present at the hospital for health care services but do not need hospital-level care before the lease arrangement is documented and signed by the parties; or
  - The daughter of a physician begins working as the hospital's paid COVID-19 outbreak coordinator before the arrangement is documented and signed by the parties.

Any party relying on the blanket waivers must document the COVID-19-related purpose and its compliance with the blanket waiver provisions.

As discussed, OIG issued a statement of policy that extended the blanket waivers to the Anti-Kickback Act. Interestingly, OIG states that it issued the statement of policy to obviate the need for parties to perform a separate anti-kickback act analysis of conduct covered by the CMS Blanket waivers.

Parties who wish to rely upon the waiver should proceed with caution, as the COVID-19 need for the waiver must be clearly documented. The waivers may be useful in allowing parties to begin arrangements prior to executing formal contracts. As with most issues involving Stark, parties should consult with counsel to determine the applicability of the waiver.

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