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CLIENT ALERT

COVID-19: DHHS Secretary Issues 1135 Blanket Waivers Applicable to Stark Law During Public Health Emergency

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On March 30, 2020, in response to the COVID-19 pandemic, Alex Azar, the Secretary of the Department of Health and Human Services (the "Secretary), used his authority under Section 1135 of the Social Security Act to waive certain requirements under Medicare, Medicaid, and the Children's Health Insurance Program (otherwise referred to as an "1135 Waiver"). While some 1135 Waivers require health care providers and suppliers to individually submit a request to the Centers for Medicare & Medicaid Services ("CMS") Regional Office seeking a waiver of particular provisions, the Secretary has the power to issue an 1135 Waiver of broad applicability to health care providers and suppliers without requiring those entities to specifically request the application of a waiver to their organization. These types of 1135 Waivers are referred to as "Blanket Waivers."

On the same day that the Secretary issued Blanket Waivers for various categories of health care providers and suppliers (e.g., hospitals, skilled nursing, home health, hospice, durable medical equipment) in a document entitled "COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers," the Secretary also issued a set of Blanket Waivers applicable to certain arrangements that otherwise might violate the federal physician self-referral law (commonly referred to as the "Stark Law") in a document entitled "Blanket Waivers of Section 1877(g) of the Social Security Act Due to Declaration of COVID-19 Outbreak in the United States as a National Emergency."

The Stark Law Blanket Waivers have a retrospective effective date of March 1, 2020. The Secretary may revise the Stark Law Blanket Waivers, from time to time, as he determines necessary, but any revisions will be effective on a prospective basis only. The Secretary or CMS may also issue additional Stark Law Blanket Waivers and ultimately terminate the Stark Law Blanket Waivers. All revisions and updates to the Stark Law Blanket Waivers will be posted on the CMS website. Therefore, any entity that relies on a Stark Law Blanket Waiver to maintain a compliant financial relationship should continue to monitor the CMS website for changes and updates. (Information on the Stark Law Blanket Waivers, and other 1135 Waivers, is currently available on a dedicated page of the CMS website.)

General Scope of Blanket Waivers Related to COVID-19 and the Stark Law

The Secretary adopted 18 Stark Law Blanket Waivers in order to ensure that there are sufficient health care items and services to meet the needs of Medicare, Medicaid, and Children's Health Insurance Program enrollees in the midst of the pandemic. The Stark Law Blanket Waivers protect health care providers that furnish designated health services "in good faith, but are unable to comply with one or more of the specified requirements" of the Stark Law and regulations. These providers 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."*

Notably, the Stark Law Blanket Waivers do not suspend the application of the Stark Law to ***all*** physician financial relationships; instead the Secretary specifically states that the Stark Law Blanket Waivers "apply only to financial relationships and referrals that are related to the national emergency that is the COVID-19 outbreak in the United States" and "must be solely related to ***COVID-19 Purposes***" (emphasis added). The Department of Health and Human Services has defined the phrase "COVID-19 Purposes" as set forth below.

Definition of "COVID-19 Purposes":

- 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 Secretary identified 18 Stark Law Blanket Waivers that apply to the following financial relationships and referrals when solely related to "COVID-19 purposes":

1. **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.

2. **Office Space 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).

3. **Office Space 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.

4. **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 equipment from the physician (or the immediate family member of the physician).

5. **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 equipment from the entity.

6. **Purchase of Items or Services from a Physician**. Remuneration from an entity to a physician (or an immediate family member of a physician) that is ***below*** FMV for items or services purchased by the entity from the physician (or the immediate family member of the physician).

7. **Purchase of Items or Services by a Physician**. Remuneration from a physician (or an immediate family member of a physician) to an entity that is ***below*** FMV 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. **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 42 CFR 411.357(m)(5)).

9. **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 set forth in 42 CFR 411.357(k)(1)).

10. **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.

11. **Loans from a Physician**. 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*** FMV, 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. **Expansion of Physician-Owned Hospitals**. 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 December 31, 2010, the effective date of such provider agreement), without prior application and approval of the expansion of facility capacity as required.

13. **Physician Ownership in Hospitals that Converted from an Ambulatory Surgery Center**. 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 certain requirements are met, which include, but are not limited to, enrolling in Medicare as a hospital during the period of the public health emergency and meeting the Medicare conditions of participation and other requirements not waived by CMS during the period of the public health emergency.

14. **Ownership in Home Health Agency**. The referral by a physician of a Medicare beneficiary for the provision of designated health services to a home health agency in which the physician (or an immediate family member of the physician) has an ownership or investment interest and which does not qualify as a rural provider.

15. **In-Office Ancillary Services (Practice Location)**. 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."

16. **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.

17. **Rural Area**. 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. **Writing Requirements**. 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.

Examples of the Application of the Stark Blanket Waivers

As part of the issuance, the Secretary provided the following examples (which are not exhaustive) of the types of remuneration, referrals, or conduct that may fall within the scope of the Stark Law Blanket Waivers. It should be noted that the Secretary clarified that unless the applicable waiver expressly applies only to a specific type of entity, the examples that include a hospital would apply to any entity that furnishes designated health services.

- 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 FMV 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 FMV 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.
- An entity sells personal protective equipment to a physician, or permits the physician to use space in a tent or other makeshift location, at below FMV (or provides the items or permits the use of the premises at no charge).
- 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, comfort items (for example, a change of clothing), or onsite child care with a value greater than $36 per instance to medical staff physicians who spend long hours at the hospital during the COVID-19 outbreak in the United States.
- An entity provides nonmonetary compensation to a physician or an immediate family member of a physician in excess of the $423 per year limit (per physician or immediate family member), such as continuing medical education related to the COVID-19 outbreak in the United States, supplies, food, or other grocery items, isolation-related needs (for example, hotel rooms and meals), child care, or transportation.

More Examples of the Application of the Stark Blanket Waivers

- 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 physician owner of a hospital lends money to the hospital to assist with operating expenses of the hospital, including staff overtime compensation, related to the COVID-19 outbreak in the United States.
- With state approval (if required), 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 in the United States.
- Consistent with its State's Emergency Preparedness or Pandemic Plan, a physician-owned ambulatory surgical center enrolls as a Medicare-participating hospital, even if it is unable to satisfy the requirements of section 1877(i)(1) of the Act, in order to provide medically necessary care to patients during the COVID-19 outbreak in the United States.
- 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.
- A group practice that meets the requirements of 42 CFR 411.352 furnishes medically necessary magnetic resonance imaging ("MRI") or computed tomography ("CT") services in a mobile vehicle, van, or trailer in the parking lot of the group practice's office to Medicare beneficiaries who would normally receive such services at a hospital, but should not go to the hospital due to concerns about the spread of the COVID-19 outbreak in the United States.
- A physician in a group practice whose principal medical practice is office-based orders radiology services that are furnished by the group practice to a Medicare beneficiary who is isolated or observing social distancing in the beneficiary's home, provided that the group practice satisfies all of the requirements of 42 CFR 411.352.
- A physician refers a Medicare beneficiary who resides in a rural area for physical therapy furnished by the medical practice that is owned by the physician's spouse and located within one mile of the beneficiary's residence.
- 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.

Recordkeeping

While parties utilizing provisions of one or more Blanket Waivers are not required to submit a specific request prior to the use of these Blanket Waivers, the Secretary sets forth that the government can request records relating to the use of the Blanket Waivers and, therefore, recommends that providers develop and maintain records in a timely manner on their use and application to financial relationships under the Stark Law.

Additional Questions

CMS sets out that those with additional questions regarding the Blanket Waivers can send an email to 1877CallCenter@cms.hhs.gov.

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