CLIENT ALERTS & INSIGHTS

Benesch COVID-19 Resource Center: CMS Blanket Waivers of the Stark Law for COVID-19 Purposes

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On March 30, 2020, the Centers for Medicare and Medicaid Services ("CMS") issued Blanket Waivers (the "Blanket Waivers") of the Federal Physician Self-Referral Law (the "Stark Law") that apply only to financial relationships and referrals related to the COVID -19 outbreak in the United States.

The Stark Law (Section 1877 of the Social Security Act, 42 C.F.R. § 411.350, *et seq.*) prohibits physicians from making a referral to an entity for the furnishing of certain designated health services payable by Medicare ("DHS") if the physician or an immediate family member of the physician has a financial relationship with the entity unless an exception applies.

The DHS covered by the Stark Law includes home health services, physical therapy, occupational therapy, speech-language pathology services, durable medical equipment, hospital inpatient and outpatient services, laboratory tests, and diagnostic imaging, among other services.

An "entity" is defined as the legal entity that furnishes the DHS or submits a claim for the DHS (a "DHS Entity"). The Stark Law also prohibits a DHS Entity from billing Medicare, Medicaid or any governmental payor for a DHS furnished as a result of the prohibited referral.

Summary of Blanket Waivers.

The Blanket Waivers and CMS's examples of the arrangements that may be protected by each Blanket Waiver are at the end of this bulletin. The Blanket Waivers are for: (a) personally performed services; (b) leases of space; (c) leases of equipment; (d) purchase or sale of items or services; (e) medical staff incidental benefits; (f) nonmonetary compensation; (g) loans; (h) temporary expansion of or conversion to a physician-owned hospital; (i) temporary non-rural, physician-owned rural home health agencies; (j) in-office ancillary services; (k) services in a patient's place of residence; (l) services to rural patients; and (m) signature and written agreements requirements.

It is important to note that the remuneration must be at or below fair market value for leases of space, leases of equipment, and purchase or sale of items or services (except for services personally performed by physicians) for the Blanket Waivers to apply.

Additionally, physicians and DHS Entities may only rely on the Blanket Waivers when the arrangement would not otherwise meet an exception to the Stark Law.

Finally, as set forth below, the Blanket Waivers only apply to certain types of "financial relationships" under the Stark Law and only to remuneration and referrals related to "COVID-19 Purposes."

Types of Financial Relationship Covered by Blanket Waivers.

The Blanket Waivers are limited to remuneration that is directly between the DHS Entity and: (a) the physician or the physician organization in whose shoes the physician stands; or (b) the immediate family member of the physician. Therefore, the Blanket Waivers do not cover "indirect compensation relationships" or "indirect ownership relationships". As set forth below, such indirect relationships will need to satisfy applicable definitional exemptions or exceptions to the Stark Law.

Additionally, as a physician may only stand in the shoes of their physician organization if they are an owner or employee, any independent contractor of a physician organization will not be covered by any Blanket Waiver that may be relied upon by the physician organization and a DHS Entity. Physician organizations and DHS Entities will have to review such arrangements under the traditional indirect compensation arrangement analysis.

An "indirect compensation relationship" exists when there exists a chain a financial relationships between a physician and the DHS Entity and the compensation arrangement closest to the physician in the chain contains remuneration that varies with the volume or value of referrals from the physician to the DHS Entity.

With respect to indirect compensation relationships between a physician and a DHS Entity, therefore, the compensation relationship in the chain closest to the physician must still be structured either: (a) to not vary with the value or volume of referrals from the physician to the DHS Entity; or (b) to comply with the Indirect Compensation Relationship Exception to the Stark Law.

With respect to indirect ownership relationships, physicians and DHS Entities will not be able to rely on the Blanket Waivers, and any indirect ownership by physicians in the DHS Entity will need to be structured to meet one of the exceptions to the Stark Law applicable to ownership.

COVID-19 Purposes.

Additionally, CMS limited the Blanket Waivers to remuneration and referrals related to COVID-19 Purposes.

CMS defined "COVID-19 Purposes" as the following:

- 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.

Documentation.

As parties relying on the Blanket Waivers must provide records relating to the use of the Blanket Waivers to CMS, it is important for physicians and DHS Entities relying on the Blanket Waivers to develop and maintain records in a timely manner. We recommend that, at a minimum, such records include the Blanket Waiver relied upon, the COVID-19 purposes served, the arrangement to be protected by the waiver, and identification of the specific physicians involved in the arrangement, including NPIs.

Fraud and Abuse Exception to the Blanket Waivers.

The Blanket Waivers do not apply in the event the government determines that there was "fraud or abuse". Therefore, we would caution health care providers to focus exclusively on furthering COVID-19 Purposes when implementing relationships and arrangements based upon the Blanket Waivers not on other unrelated business opportunities or interests.

Term of the Blanket Waivers.

The effective date of the blanket is March 1, 2020. The Blanket Waivers will terminate after the expiration of the Secretary's authority to grant waivers for the COVID-19 outbreak. At that time, physicians and DHS Entities will once again need to comply fully with the Stark Law.

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For further information regarding the Blanket Waivers or assistance with implementing arrangements using the Blanket Waivers, please reach out to W. Clifford Mull, Frank W. Carsonie, or any other member of the Benesch Healthcare+ team.

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The Blanket Waivers: Summary of Information Included in CMS's Announcement.

The Blanket Waivers apply to the following arrangements, relationships or referrals:

1. **Personal Services of Physicians**
    - Waiver. 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.
    - Example. A hospital pays physicians above their previously-contracted rate for furnishing professional services for COVID-19 patients in particularly hazardous or challenging environments.

2. **Lease of Space from Physicians**

   - Waiver. 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).
   - Examples.
     - To accommodate patient surge, a hospital rents office space 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.

3. **Lease of Equipment from Physicians**

   - Waiver. 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).
   - Example. To accommodate patient surge, a hospital rents equipment from an independent physician practice at below fair market value or at no charge.

4. **Purchase of Items from Physician**

   - Waiver. 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).
   - Example. 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.

5. **Lease of Space by Physician**

   - Waiver. 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.
   - Example. 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.

6. **Lease of Equipment by Physician**

   - Waiver. 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.
   - Example. 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.

7. **Purchase of Space or Items by Physician**

   - Waiver. 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.
   - Example. 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 fair market value (or provides the items or permits the use of the premises at no charge).

8. **No Limits on Medical Staff Incidental Benefits**

   - Waiver. Remuneration from a hospital to a physician in the form of medical staff incidental benefits that exceeds the limit set forth in Medical Staff Incidental Benefits Exception to the Stark Law, 42 CFR 411.357(m)(5).
   - Examples:
     - 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.

9. **No Limits on Nonmonetary Compensation**

   - Waiver. Remuneration from an entity to a physician (or the immediate family member of a physician) in the form of nonmonetary compensation that exceeds the limit set forth in the Nonmonetary Compensation Exception to the Stark Law, 42 CFR 411.357(k)(1).
   - Example. 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.

10. **Loans to Physicians**

   - Waiver. 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):
     - with an interest rate below fair market value; or
     - on terms that are unavailable from a lender that is not a recipient of the physician's referrals or business generated by the physician.
   - Example. 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.

11. **Loans from Physicians**

   - Waiver. Remuneration from a physician (or the immediate family member of a physician) to an entity resulting from a loan to the entity:
     - with an interest rate below fair market value; or
     - 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).
   - Example. 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.

12. **Temporary Expansion of Physician-Owned Hospitals**

- Waiver. 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 under section 1877(i)(1)(B) and (i)(3) of the Act and 42 CFR 411.362(b)(2) and (c).
- Example. 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.

13. **Conversion of Physician-Owned ASC to Physician-Owned Hospital**

- Waiver. 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:
  - the hospital does not satisfy one or more of the requirements of section 1877(i)(1)(A) through (E) of the Act;
  - the hospital enrolled in Medicare as a hospital during the period of the public health emergency described in section II.A of this Blanket Waiver document;
  - the hospital meets the Medicare conditions of participation and other requirements not waived by CMS during the period of the public health emergency described in section II.A of this Blanket Waiver document; and
  - the hospital's Medicare enrollment is not inconsistent with the Emergency Preparedness or Pandemic Plan of the State in which it is located.

- Example. 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.

14. **Non-rural, Physician-Owned Home Health Agency**

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

- Example. 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.

15. **In-office Ancillary Services Furnished Outside of a Centralized Building or Same "Building"**

- Waiver. 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).
- Example. 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.

16. **Services Furnished in a Patient's Home**

- Waiver. 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.
- Example. 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.

17. **Patients Residing in Rural Area**

- Waiver. 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.
- Example. 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.

18. **Signed, Written Agreements Waived**

- Waiver. 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.
- Examples. 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.

If you have any questions regarding the content above, please contact a member of your Benesch team.

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Please note that this information is current as of the date of this Client Alert, based on the available data. However, because COVID-19's status and updates related to the same are ongoing, we recommend real-time review of guidance distributed by the CDC and local officials.

