



## Health Care ADVISORY ■

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### CMS Issues Blanket Waivers from Physician Self-Referral Law Sanctions

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On March 30, 2020, in response to the coronavirus (COVID-19) pandemic, the Centers for Medicare & Medicaid Services (CMS) announced [blanket waivers of sanctions](#) imposed by Section 1877(g) of the Social Security Act (and associated regulations), also known as the physician self-referral law. The physician self-referral law prohibits a physician from making Medicare or Medicaid patient referrals for certain designated health services (DHS) to an entity that physician (or the physician's immediate family member) has a financial relationship with, unless an applicable exception applies. The enumerated blanket waivers issued by CMS allow physicians, hospitals, physician organizations, and various entities the flexibility to adjust their financial arrangements to better respond to the strain currently placed on our health care system by temporarily removing some existing regulatory hurdles. The waivers further CMS's goal of ensuring sufficient health care services are available during the COVID-19 public health emergency, while providing reimbursement for DHS claims that, but for satisfying the conditions of a waiver, would otherwise be in violation of the physician self-referral law.

The Department of Health and Human Services (HHS) granted the waivers pursuant to Section 1135 of the Social Security Act.

#### **Applicability of the Blanket Waivers**

The blanket waivers only provide protection from sanctions for financial relationships and referrals that are related to the COVID-19 outbreak in the U.S. CMS placed several conditions on the applicability of the waivers:

- Any remuneration described by the blanket waivers must be exchanged directly between the DHS entity and:
  - The physician (or the physician organization in whose shoes the physician stands); or
  - The immediate family member of the physician.
- The remuneration and referrals covered by the blanket waivers must be "solely related to COVID-19 Purposes."

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“COVID-19 Purposes” means:

- 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 Blanket Waivers**

CMS issued 18 blanket waivers, which are retroactively effective to March 1, 2020 and apply nationwide. *References to “physician” below should be read to include any immediate family member of the physician.*

### ***Waiver for personally performed services***

Remuneration from an entity to a physician that is above or below the fair market value for services personally performed by the physician to the entity.

### ***Waivers for certain rental rates***

Rental charges paid by an entity to a physician that are below fair market value for the entity’s lease of office space from the physician.

Rental charges paid by an entity to a physician that are below fair market value for the entity’s lease of equipment from the physician.

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***Waivers for purchase of items and services***

Remuneration from an entity to a physician that is below fair market value for items or services purchased by the entity from the physician.

Remuneration from 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 from the entity.

***Waivers for certain physician compensation arrangements***

Remuneration from a hospital to a physician in the form of medical staff incidental benefits that exceeds the limit set forth in 42 C.F.R. 411.357(m)(5).

Remuneration from an entity to a physician in the form of nonmonetary compensation that exceeds the limit set forth in 42 C.F.R. 411.357(k)(1).

Remuneration from an entity to a physician resulting from a loan to 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.

Remuneration from 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.

***Waivers based on type of facility***

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 the effective date of a provider agreement in effect on December 31, 2010) without prior application and approval of the expansion of facility capacity as required under Sections 1877(i)(1)(B) and (i)(3) and 42 C.F.R. 411.362(b)(2) and (c).

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: (1) the hospital does not satisfy one or more of the requirements of Section 1877(i)(1)(A) through (E); (2) the hospital enrolled in Medicare as a hospital during the period of the COVID-19 public health emergency; (3) the hospital meets the Medicare conditions of participation and other requirements not waived by CMS during the period of the COVID-19 public health emergency; and (4) the hospital's Medicare enrollment is not inconsistent with the emergency preparedness or pandemic plan of the state where it is located.

The referral by a physician of a Medicare beneficiary for the provision of DHS to a home health agency: (1) that does not qualify as a rural provider under 42 C.F.R. 411.356(c)(1); and (2) in which the physician has an ownership or investment interest.

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

***Waivers for certain restrictions related to group practices***

The referral by a physician in a group practice for medically necessary DHS furnished by the group practice in a location that does not qualify as a “same building” or “centralized building” for purposes of 42 C.F.R. 411.355(b)(2).

The referral by a physician in a group practice for medically necessary DHS furnished by the group practice to a patient in his or her private home, 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.

***Waiver for failure to satisfy written requirement***

Referrals by a physician to an entity the physician has a compensation arrangement with that does not satisfy the writing or signature requirements of an applicable exception but satisfies each other requirement of the applicable exception, unless such requirement is waived under one or more of the other blanket waivers.

**Important Things to Know About the Blanket Waivers**

**Duration.** The blanket waivers terminate at the conclusion of the COVID-19 nationwide public health emergency declaration or on the date of any potential extension to the blanket waivers.

**Prospective Application of Revisions.** The blanket waivers may be revised if deemed necessary by the HHS Secretary. If any revisions narrow a blanket waiver, or terminate the blanket waivers, the revisions will only be effective prospectively.

**Conditions Precedent.** Each blanket waiver is limited to the description contained in that waiver. All conditions required by each blanket waiver must be satisfied for a health care provider to use or rely on the particular waiver.

**No Reporting Requirement.** Health care providers need not submit documentation or notice to the HHS Secretary or CMS before the use of or reliance on the blanket waivers.

**Recordkeeping.** CMS encourages parties relying on the waivers to timely develop and maintain records related to such arrangements as a best practice. Health care providers must make such records available to the HHS Secretary on request.

**Acknowledge Existing Exceptions.** Health care providers should be aware that the use of any blanket waiver may not be necessary for all financial relationships related to COVID-19 Purposes because some existing exceptions to the physician self-referral law could apply to their particular current or anticipated financial arrangement.

## Key Takeaways

**Existing Exceptions Still Available:** CMS reminds DHS entities that reliance on the blanket waivers may not be necessary because many financial relationships related to COVID-19 Purposes may satisfy the requirements of an existing exception to the Stark Law. DHS providers may consider whether the proposed arrangement can satisfy an existing Stark Law exception before utilizing a blanket waiver.

**Documentation:** DHS entities need to document their use of the blanket waivers. DHS providers should consider using a form to ensure all relevant information is captured.

**AKS Requirements Not Waived:** Sanctions for noncompliance are waived with the blanket waivers, provided there is no determination by the government of fraud or abuse. This means that the use of the waiver may later be analyzed under the Anti-Kickback Statute. Consequently, DHS entities should never base their decision to use a blanket waiver on the volume or value of referrals from the physician and should document the nonreferral reason for use of the blanket waivers.

**Still Some Difficult Calls:** Use of the blanket waivers may be an easy call in some situations, such as reducing rent for physicians in a hospital-owned medical office building when the physicians and physician practices have experienced a significant reduction in patient volume due to the coronavirus pandemic and they provide services in a COVID-19-related practice area. Other situations may be more complex, such as determining what level of compensation to provide to employed physicians who are not directly involved in treatment of COVID-19 patients and who do not participate in the care of COVID-19 patients. Hospitals should seek legal counsel to further analyze complex or marginal requests.

**Lack of Other Agency Guidance:** The enumerated COVID-19 Purposes clearly contemplate using the blanket waivers with physicians providing care to COVID-19 patients. The COVID-19 Purposes also appear to contemplate situations where a blanket waiver may be used with physicians who are not providing care to COVID-19 patients. Unlike regulations, where the contours of an exception are further explained in the preamble to the regulation, the blanket waivers do not provide further guidance on situations when CMS considers use of a blanket waiver to be appropriate for a physician who is not treating COVID-19 patients. Since this is an ambiguous area, DHS entities should consider seeking legal counsel to further analyze the request.

**Potential for Individual Waivers:** If it is unclear whether a blanket waiver applies to a particular situation, the DHS entity may seek clarification and an individual waiver from CMS.

Alston & Bird has formed a multidisciplinary [task force](#) to advise clients on the business and legal implications of the coronavirus (COVID-19). You can [view all our work](#) on the coronavirus across industries and [subscribe](#) to our future webinars and advisories.

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