LEGAL UPDATES

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CMS Issues Blanket Waivers of Section 1877(g) of the Social Security Act

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Due to the COVID-19 pandemic, the Centers for Medicare & Medicaid Services (CMS) has issued blanket waivers of sanctions under the federal Physician Self-Referral Law (also known as the Stark Law) with respect to specific "COVID-19 Purposes." These waivers are retroactively effective from March 1, 2020, and apply nationwide. During the time the blanket waivers are in effect, CMS will pay claims for designated health services (DHS) that otherwise would violate the Stark Law without the blanket waiver.

Background: Section 1135 waivers and the Stark Law

Waivers under Section 1135 of the Social Security Act require two prerequisites, both of which were satisfied as of March 13, 2020. First, the President must have declared an emergency or disaster under the Stafford Act or the National Emergencies Act; second, the Secretary of Health and Human Services must have declared a Public Health Emergency under Section 319 of the Public Health Service Act.

The Stark Law prohibits a physician from making referrals for certain DHS payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless all of the requirements of an applicable exception are satisfied and prohibits the entity from filing claims with Medicare (or billing another individual, entity or third-party payor) for DHS furnished pursuant to a prohibited referral. Financial relationships can be ownership or investment interests in the entity or can be a compensation arrangement with the entity.

COVID-19 blanket waivers

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Section 1135(b) of the Social Security Act grants the Secretary power to waive or modify application of the sanctions described in Section 1877(g) of the Act to ensure that sufficient healthcare items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid and Children's Health Insurance programs. In addition, the waivers serve to allow healthcare providers—who furnish such items and services in good faith but are unable to comply with the requirements of Section 1877 of the Act as a result of the COVID-19 pandemic—to be reimbursed for such items and services (absent a government determination of any fraud or abuse).

Pursuant to Section 1135(e) of the Act, the blanket waivers will conclude upon the termination of the applicable declaration of emergency or disaster, the termination of the applicable declaration of public health emergency, or termination of a period of 60 days from the date the waiver or modification is first published. CMS requires that parties utilizing the blanket waivers must make records relating to the use of the blanket waivers available to the Secretary upon request.

According to the CMS document, the remuneration described in the blanket waivers must be "directly between the entity and (1) the physician or the physician organization in whose shoes the physician stands under 42 CFR 411.354(c) OR (2) the immediate family member of the physician." Therefore, based on this language and the specifically enumerated situations of remuneration, referrals and conduct subject to the blanket waivers, it does not appear that CMS intends to apply the blanket waivers to indirect compensation arrangements.

The remuneration and referrals must be solely related to specifically defined "COVID-19 Purposes," which are limited to 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 healthcare 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 healthcare providers to address patient and community needs due to the COVID-19 outbreak in the United States;

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

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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 charts below briefly summarize how remuneration by an entity or physician for various items will be treated by the blanket waivers:

DHS Entity Payments	**Waiver**
Personal Services	Above or below fair market value (FMV) Permitted
Office Space	Below FMV Permitted
Equipment	Below FMV Permitted
Items or Services	Below FMV Permitted
Medical Staff Incidental Benefits	Above $25 Permitted
Nonmonetary Compensation	Above $300/year Permitted
Loans to a Physician	Below FMV Permitted
Physician Payments	**Waiver**
Office Space	Below FMV Permitted
Equipment	Below FMV Permitted
Items or Services	Below FMV Permitted
Use of Entity Premises	Below FMV Permitted
Loans to an Entity	Below FMV Permitted

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In addition, CMS also defines various referrals that are subject to the blanket waivers of Section 1877(g) of the Act, including the following:

Referrals by a Physician	Waiver
By a physician owner of a hospital	To temporarily expand hospital's facility capacity without prior application and approval
By a physician owner of a hospital	To a hospital that converted from a physician-owned ambulatory surgical center to a hospital on or after March 1, 2020
By a physician of a Medicare beneficiary	For the provision of DHS by a home health agency
By a physician in a group practice	For medically necessary DHS 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)
By a physician in a group practice	For medically necessary DHS to a patient in his/her private home, an assisted living facility, or independent living facility if physician's practice does not consist of treating patients in their private homes
By a physician to an entity	Where the physician's immediate family member has a financial relationship with the entity, if the patient who is referred resides in a rural area
By a physician to an entity	Where there is compensation arrangement that does not satisfy the writing or signature requirement(s) of a particular exception

The document also includes two pages of examples of remuneration, referrals or conduct that may fall within the scope of the blanket waivers. Importantly, CMS states that the examples provided in the document are illustrative only and not an exhaustive list of situations that would qualify for the waiver

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of sanctions.

Individual waivers of sanctions under Section 1877(g) of the Act may be granted upon request via email to 1877CallCenter@cms.hhs.gov. Requests should include the words “Request for 1877(g) Waiver” in the subject line. All requests should include the following minimum information:

Name and address of requesting entity

Name, phone number and email address of person designated to represent the entity

CMS Certification Number (CCN) or Taxpayer Identification Number (TIN) of the requesting entity

Nature of request

Importantly, unless and until a waiver of sanctions is granted to the requesting party, such party must comply with section 1877 of the Act and the regulations at 42 C.F.R. § 411.350 et seq.

Contact us

If you would like more information on the applicability and implications of the blanket waivers to your business model, please contact your Husch Blackwell healthcare attorney.

COVID-19 resource

Husch Blackwell has launched a COVID-19 response team providing insight to businesses as they address challenges related to the coronavirus outbreak. The page contains programming and content to assist clients and other interested parties across multiple areas of operations, including labor and unemployment, retailing, and supply chain management, among others.

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