WHO: The Secretary of the Department of Health and Human Services (HHS)

WHAT: Issued nationwide “blanket waivers” of the federal Stark Law (Section 1877 of the Social Security Act) pursuant to his authority Section 1135 of the Social Security Act.

WHEN: Although issued on March 30, 2020, the waivers are retroactively effective as of March 1, 2020.

WHY: HHS is waiving sanctions under the Stark Law and its underlying regulations to ensure that: (1) sufficient health care items and services are available to meet the needs of individuals enrolled in federal healthcare programs, and (2) health care providers that furnish such items and services in good faith, but are unable to comply fully with the Stark Law’s requirements as a result of the consequences of
the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for noncompliance.

**HOW**: The waiver is available to protect financial relationships that satisfy two criteria: (1) the remuneration and referrals must be solely related to “COVID-19 Purposes”; and (2) the referrals and claims must be related to a defined set of financial relationships, as set forth below.

## 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 professional 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 availability 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 of the United States

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.

## APPLICABLE FINANCIAL RELATIONSHIPS

**Personally Performed Services.** A waiver for *above or below* fair market value compensation from an entity to a physician for services personally performed by the physician.

**Below FMV Compensation.** Waivers for compensation that is *below* fair market value with respect to:
• Rental charges paid by an entity to a physician for the entity’s lease of office space or equipment.

• Rental charges paid by a physician to an entity for the physician’s lease of office space or equipment.

• Remuneration from an entity to a physician, or from a physician to an entity, for purchased items or services.

**Medical Staff Incidental Benefits.** A waiver for medical staff incidental benefits provided by a hospital to a physician with a value that exceeds $36.00 per occurrence in calendar year 2020.

**Nonmonetary Compensation.** A waiver for nonmonetary compensation provided by an entity to a physician that exceeds $423.00 in calendar year 2020.

**Loans with Favorable Terms.** Waivers for remuneration resulting from loans by an entity to a physician, or by a physician to an entity, that include:

• An interest rate that is below FMV; or

• Terms that are not available from a lender that is not a recipient of referrals, or in a position to generate business for, the lender.

**Physician-Owned Hospitals.** Waivers for referrals by a physician-owner of a hospital to:

• 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 otherwise “grandfathered” in under the physician-owned hospital exception) without prior application and approval of the expansion; and

• A hospital that converted from a physician-owned ambulatory surgery center to a hospital on or after March 1, 2020; provided that the hospital satisfies certain requirements related to enrollment in the Medicare program.

**Physician-Owned Home Health Agency.** A waiver for a physician’s referral of a Medicare beneficiary for designated health services to a home health agency that:

• The physician has an ownership or investment interest in; and
• Does not qualify as a rural provider under 42 C.F.R. 411.356(c)(1)

**Location of Group Practice Services.** Waivers for referrals 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 C.F.R. 411.355(b)(2); or

• To a patient in the patient’s 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.

**Immediate Family Members and Rural Area.** A waiver for referrals 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.

**Lack of Writing.** A waiver for referrals by a physician to an entity with whom the physician has a compensation arrangement that does not satisfy the writing requirement of an applicable exception, but satisfies every other requirement of an applicable exception (unless such requirement is waived under one or more of the blanket waivers identified above).

**OTHER IMPORTANT INFORMATION.**

• The Stark Law blanket waivers may be revised from time to time as determined necessary by the Secretary of HHS.

• CMS may issue additional blanket waivers.

• Revised or additional blanket waivers will be posted on the Centers for Medicare & Medicare services website.

• Revisions that narrow or terminate a blanket waiver will be effective on a prospective basis only.

• Additional blanket waivers will be effective on the date identified when the waiver is issued.

• Records relating to the use of the blanket waivers must be made available to the Secretary of HHS upon request. Parties intending to take advantage of a waiver are encouraged to develop and maintain records documenting the arrangement in a timely manner.

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