

THE STARK LAW BLANKET WAIVERS

HOW THESE APPLY TO COVID-19



By Chandler Martin

In response to the COVID-19 pandemic, on March 30, 2020, Centers for Medicare and Medicaid Services (“CMS”) issued blanket waivers of sanctions under Section 1877 of the Social Security Act (the “Stark Law”). The waivers are effective retroactively as of March 1, 2020. The full text of the blanket waivers is available from CMS at this link: [Blanket Waivers of the Stark Law Due to COVID-19 National Emergency](#). The issuance document from CMS provides the full scope and application of the Stark Law blanket waivers, which we have summarized below.

While the Stark Law blanket waivers are in effect, CMS will pay claims for designated health services (as defined under the Stark Law) that, but for satisfying the

conditions of a blanket waiver, would violate the Stark Law. The 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, as detailed below. Absent compliance with a blanket waiver, the Stark Law and its sanctions still apply as usual. Thus, any arrangement to which the Stark Law applies during the waiver period must satisfy either an applicable Stark Law exception or the requirements of a blanket waiver.

Background: Section 1135 Waivers and the Stark Law

The Stark Law blanket waivers arose from the Secretary of the United States Department of Health and Human Services (the “Secretary”) invoking the Secretary’s

waiver authority under Section 1135 of the Social Security Act (“Section 1135”).

The two prerequisites for the Secretary invoking waiver authority under Section 1135 were met as of March 13, 2020, as a result of the COVID-19 pandemic — the President has declared an emergency or disaster under either the Stafford Act or the National Emergencies Act and the Secretary has declared a Public Health Emergency under Section 319 of the Public Health Service Act. The emergency area in this case is the entire United States. Accordingly, under Section 1135, the Secretary has the authority to grant waivers to ensure (i) that sufficient health care items and services are available to meet the needs of individuals in the United States enrolled in the Medicare, Medicaid, and CHIP programs; and (ii) that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of the specified requirements of the Stark Law as a result of the consequences of the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent the government’s determination of fraud or abuse.

The Stark Law: (1) prohibits a physician from making referrals for certain designated health services 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 (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payor) for designated health services fur-

nished pursuant to a prohibited referral. A financial relationship under the Stark Law includes an ownership or investment interest in the entity or a compensation arrangement with the entity. Exceptions to the Stark Law are set forth at 42 CFR 411.355 through 411.357. To comply with the Stark Law, an implicated arrangement must satisfy each and every requirement of an applicable Stark Law exception.

The requirements for a Stark Law exception can be numerous and complex. Because of its general prohibitions and detailed exception requirements, the Stark Law limits the ability of entities that provide designated health services to enter into certain financial arrangements with physicians, as well as the ability of physicians to freely refer patients for designated health services.

Stark Law Blanket Waivers During COVID-19 Emergency

Pursuant to Section 1135, the Stark Law blanket waivers will terminate upon the termination of the president’s declaration

of emergency, the termination of the Secretary’s declaration of public health emergency, or termination of a period of 60 days from the date the waiver or modification was first published.

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. Specifically, the remuneration and referrals (i.e., the arrangement to which the Stark Law applies) described in the blanket waivers must be solely related to “COVID-19 Purposes.” For purposes of the blanket waivers, 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 services in response to the COVID-19 outbreak;

Ensuring the ability of healthcare providers to address patient and community needs due to the COVID-19 outbreak;

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

Shifting the diagnosis and care of patients to appropriate alternative settings due to the COVID-19 outbreak; or

Addressing medical practice or business interruption due to the COVID-19 outbreak in order to maintain the availability of medical care and related services for patients and the community.

Contact Us

If you have any questions or would like more information on the applicability and implications of the Stark Law blanket waivers or the Stark Law generally, please contact Chandler Martin, at 803-540-2161 or cmartin@nexsenpruet.com, or your regular Nexsen Pruet attorney. ✉



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