



April 3, 2020

COVID-19 Stark Law Waivers

Summary

On March 30, 2020, the Secretary of the U.S. Department of Health and Human Services (the “*Secretary*”) issued nationwide blanket Stark Law waivers, retroactive to March 1, 2020 (the “*Blanket Stark Law Waivers*”).¹ The Blanket Stark Law Waivers expire after expiration of the authority of the Secretary to grant waivers for the COVID-19 outbreak in the United States. The Blanket Stark Law Waivers are set forth, categorized and explained in the Table below.

Background

As mentioned in our prior alert, on March 13, 2020, as a result of the public health emergency and national emergency declarations regarding COVID-19, the Secretary issued several waivers pursuant to Section 1135 of the Social Security Act (SSA), which waived or modified certain Medicare, Medicaid, and Children’s Health Insurance Program (CHIP) program requirements and conditions of participation, retroactive to March 1, 2020.² These Section 1135 waivers included, among others, a waiver of sanctions under Section 1877(g) of the SSA for violations of Section 1877 of the SSA (otherwise known as the Stark Law), as determined appropriate by the Centers for Medicare and Medicaid Services (CMS).

Unlike its approach to other particular program requirements and conditions of participation, CMS did not issue additional guidance or blanket waivers of the Stark Law immediately after issuance of the Section 1135 waivers. This was consistent with CMS’s practice with respect to Stark Law waivers in prior public health emergencies, requiring providers to request waivers of the Stark Law on a case-by-case basis through a process whereby the provider was required to provide specific details concerning the actual or proposed financial relationship between the referring physician(s) and the entity furnishing designated health services (DHS).³

However, believing CMS’s existing practice was not practical or appropriate for the COVID-19 public health emergency, the American Hospital Association (AHA) asked CMS to issue a blanket Stark Law waiver, stating:

By interim final rule with comment period or exercise of its waiver authority, CMS should immediately adopt an exception to the definition of “compensation arrangement” under 42 USC 1395nn for any compensation paid to a physician or a physician’s immediate family member in return for a service necessary to the hospital’s response to the COVID-19 public health crisis.⁴

¹ A copy of the Blanket Stark Law Waivers is available [here](#).

² More information regarding the Section 1135 waivers can be found [here](#).

³ Approximately a year ago, CMS released guidance setting forth its historic practice of granting Stark Law waivers on a case-by-case basis in the context of public health emergencies (the “*Prior Stark Law Emergency Waiver Guidance*”). The Prior Stark Law Emergency Waiver Guidance can be found [here](#).

⁴ A link to the AHA letter is available [here](#). In the letter, the AHA also requested Anti-Kickback Statute (42 U.S.C. §1320a-7b(b)) relief, stating (emphasis original):

OIG, in coordination with the Department of Justice (DOJ), should make clear by whatever means are appropriate that any transaction between hospitals, physicians and other potential referral sources, or any vendor who delivers services and supplies to hospitals, that has as its primary purpose the delivery of supplies or services necessary to the hospital’s response to the COVID-19 public health crisis will not be subject to prosecution or sanctions under the Anti-Kickback Statute or civil monetary penalties law. In addition, similar action should be taken to make clear that hospital support for patients that is necessary in responding to the COVID-19 public health crisis will not be subject to prosecution or sanctions under the Anti-Kickback Statute or civil monetary penalties law.

The OIG did post a letter on its website dated March 30, 2020 (the same date that the Blanket Stark Law Waivers were issued), though it is not clear whether the OIG’s letter was in response to the AHA letter. In its letter, the OIG notes that it will carefully consider the

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Seemingly responding to AHA's request, the Secretary issued the Blanket Stark Law Waivers on March 30, 2020, retroactive to March 1, 2020.

CMS notes that the Blanket Stark Law Waivers may be revised from time to time as determined by CMS and that any such revisions will be posted on CMS's website, with any revisions that narrow or terminate a blanket waiver being effective only on a prospective basis and any additional blanket waivers being effective as of the date stated in the additional waiver. Parties must meet all conditions of the Blanket Stark Law Waiver in order to rely on the waiver and each Blanket Stark Law Waiver is limited to the circumstances set forth in the waiver. If a Blanket Stark Law Waiver applies, CMS will pay claims for DHS that would otherwise violate the Stark Law.

CMS notes that parties utilizing the Blanket Stark Law Waivers are required to make records relating to such use available to the Secretary on request. CMS further notes that, although the Blanket Stark Law Waivers may be used retroactive to March 1, 2020 and do not require the submission of specific documentation or notice to the Secretary or CMS in advance of their use, CMS encourages parties to develop and maintain records in a timely manner as a best practice.

CMS sets forth the following conditions with respect to use of the Blanket Stark Law Waivers:

- The Blanket Stark Law waivers have retroactive effect to March 1, 2020, may be used nationwide and expire as after expiration of the Secretary's authority to grant waivers for the COVID-19 outbreak in the United States.
- The Blanket Stark Law Waivers apply only to financial relationship and referrals that are related to the COVID-19 outbreak in the United States.
- Any remuneration described in the Blanket Stark Law Waivers must be directly between the DHS entity and either (i) the physician or the physician organization in whose shoes the physician stands under 42 C.F.R. 411.354(c) or (ii) the immediate family member of the physician.
- The remuneration and referrals described in the Blanket Stark Law Waivers must be solely related to "COVID-19 Purposes," which 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 order to maintain the availability of medical care and related services for patients and the community.

context and intent of the parties when assessing whether to proceed with any enforcement action with respect to any conduct during the COVID-19 emergency that may be subject to OIG administrative enforcement. The OIG letter is available [here](#).

The following table categorizes the Blanket Stark Law Waivers and reproduces CMS’s examples of the waivers.

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<u>BLANKET STARK LAW WAIVERS</u>		
Waiver Category	Waiver Language	Examples
Items/Services	<ul style="list-style-type: none"> • <u>Blanket Stark Law Waiver 1</u>: 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. • <u>Blanket Stark Law Waiver 4</u>: 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). 	<ul style="list-style-type: none"> • <i>Example A</i>: A hospital pays physicians above their previously-contracted rate for furnishing professional services for COVID-19 patients in particularly hazardous or challenging environments. • <i>Example B</i>: 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.
Office Space Rental Charges	<ul style="list-style-type: none"> • <u>Blanket Stark Law Waiver 2</u>: 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). • <u>Blanket Stark Law Waiver 5</u>: 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. 	<ul style="list-style-type: none"> • <i>Example C</i>: To accommodate patient surge, a hospital rents office space or equipment from an independent physician practice at below fair market value or at no charge. • See also <i>Examples E</i> and <i>F</i> below
Equipment Rental Charges	<ul style="list-style-type: none"> • <u>Blanket Stark Law Waiver 3</u>: 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). • <u>Blanket Stark Law Waiver 6</u>: 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. 	<ul style="list-style-type: none"> • <i>Example D</i>: 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. • See also <i>Example C</i> above.
Premises License and Items/Services	<ul style="list-style-type: none"> • <u>Blanket Stark Law Waiver 7</u>: 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. 	<ul style="list-style-type: none"> • <i>Example E</i>: 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.

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		<ul style="list-style-type: none"> • <i>Example F:</i> 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. • <i>Example G:</i> 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). • <i>Example H:</i> 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.
Medical Staff and Nonmonetary Compensation	<ul style="list-style-type: none"> • <u>Blanket Stark Law Waiver 8:</u> Remuneration from a hospital to a physician in the form of medical staff incidental benefits that exceeds the limit set forth in 42 CFR 411.357(m)(5). • <u>Blanket Stark Law Waiver 9:</u> 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 42 CFR 411.357(k)(1). 	<ul style="list-style-type: none"> • <i>Example I:</i> 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. • <i>Example J:</i> 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.
Loans	<ul style="list-style-type: none"> • <u>Blanket Stark Law Waiver 10:</u> 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): (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. 	<ul style="list-style-type: none"> • <i>Example K:</i> 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

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	<ul style="list-style-type: none"> • <u>Blanket Stark Law Waiver 11</u>: Remuneration from a physician (or the immediate family member of 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 (or the immediate family member of the physician). 	<p>health records (EHR) items and services in order to continue the physician’s access to patient records and ongoing EHR technology support services.</p> <ul style="list-style-type: none"> • <i>Example L</i>: 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.
Hospital Ownership Exceptions	<ul style="list-style-type: none"> • <u>Blanket Stark Law Waiver 12</u>: 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). • <u>Blanket Stark Law Waiver 13</u>: 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: (i) the hospital does not satisfy one or more of the requirements of section 1877(i)(1)(A) through (E) of the Act; (ii) 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; (iii) 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 (iv) the hospital’s Medicare enrollment is not inconsistent with the Emergency Preparedness or Pandemic Plan of the State in which it is located.⁵ 	<ul style="list-style-type: none"> • <i>Example M</i>: 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. • <i>Example N</i>: 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.

⁵ This Blanket Stark Law Waiver was issued in relation to CMS’s decision to allow currently enrolled ambulatory surgery centers to temporarily enroll as hospitals and provide hospital services to help address the urgent need for increased hospital capacity to care for patients. Additionally, under this initiative, other interested entities, such as freestanding emergency departments, can pursue enrolling in Medicare as an ambulatory surgery center and then convert their enrollment to a hospital during the COVID-19 public health emergency. More information about these initiatives, as well as CMS’s “Hospital Without Walls Initiative” is available [here](#). Ambulatory surgery centers that wish to enroll to receive temporary billing privileges as a hospital are encouraged to call the COVID-19 Provider Enrollment Hotline to reach the contractor that serves their jurisdiction and then complete and sign an attestation form specific to the COVID-19 public health emergency. More information concerning these Provider Enrollment Hotlines is available in our previously issued Client Alert addressing Provider Enrollment Flexibilities, available [here](#).

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Waiver Category	Waiver Language	Examples
<p>Home Health Agency</p>	<ul style="list-style-type: none"> • <u>Blanket Stark Law Waiver 14</u>: The referral by a physician of a Medicare beneficiary for the provision of designated health services to a home health agency: (1) that does not qualify as a rural provider under 42 CFR 411.356(c)(1); and (2) in which the physician (or an immediate family member of the physician) has an ownership or investment interest 	<ul style="list-style-type: none"> • <i>Example O</i>: 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
<p>Group Practice</p>	<ul style="list-style-type: none"> • <u>Blanket Stark Law Waiver 15</u>: 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). • <u>Blanket Stark Law Waiver 16</u>: 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. 	<ul style="list-style-type: none"> • <i>Example P</i>: 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. • <i>Example Q</i>: 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.
<p>Rural Area</p>	<ul style="list-style-type: none"> • <u>Blanket Stark Law Waiver 17</u>: 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. 	<ul style="list-style-type: none"> • <i>Example R</i>: 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.
<p>Writing/ Signature Requirements</p>	<ul style="list-style-type: none"> • <u>Blanket Stark Law Waiver 18</u>: 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. 	<ul style="list-style-type: none"> • <i>Example S</i>: 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: <ul style="list-style-type: none"> ○ A physician provides call coverage services to a hospital before the

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		<p>arrangement is documented and signed by the parties;</p> <ul style="list-style-type: none"> ○ 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.

Individual Stark Law Waivers

For arrangements that do not fall under the Blanket Stark Law Waivers, CMS makes clear that individual Stark Law waivers (“*Individual Stark Law Waivers*”) are also available and may be granted upon request. CMS outlines the following process for requesting an Individual Stark Law Waiver:

- The request must be sent via email to 1877CallCenter@cms.hhs.gov and include the words “Request for 1877(g) Waiver” in the subject line.
- All requests should include the following 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; and
 - Nature of request.

We expect that CMS will respond to a request for an Individual Stark Law Waiver within three business days of its receipt of the request, as this was the timeline set forth in the Prior Stark Law Emergency Waiver Guidance, though this is not clear.

CMS does make clear, however, that unless and until the parties to an arrangement meet the conditions of a Blanket Stark Law Waiver or have been granted an Individual Stark Law Waiver from CMS, the parties are required to comply with the Stark Law and otherwise will face sanctions, even in the context of a national public health emergency.

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Kutak Rock attorneys are actively engaged in monitoring the legal changes as a result of COVID-19, including the legislative and regulatory actions that have been taken. We have prepared a number of client alerts and special publications relating to COVID-19 which can be accessed on [Kutak Rock's COVID-19 Legal Resource Portal](#). In addition, determining whether an arrangement meets the requirements of a Blanket Stark Law Waiver, or requesting Individual Stark Law Waivers with respect to an arrangement, requires experienced healthcare counsel. If you have any questions about this Alert or about the impact of COVID-19 on your business, please contact a member of our [national Healthcare practice group](#). We stand available and willing to assist you during this unprecedented time in our nation's history.

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