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Section 1135 Waivers Provide Some Regulatory Flexibility for Healthcare Providers

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Under Section 1135 of the Social Security Act, the Secretary of the U.S. Department of Health & Human Services ("Secretary") is authorized to waive or modify certain federal regulatory requirements when two prerequisites are met: (1) the President has declared an emergency or disaster under either the Stafford Act or the National Emergencies Act (met on March 13, 2020 when the President declared a nationwide emergency under the Stafford Act), and (2) the Secretary has declared a public health emergency ("PHE") under Section 310 of the Public Health Service Act (met on January 31, 2020 when the Secretary declared a PHE).

As a result of this authority, the Secretary can issue several types of 1135 waivers, including (i) blanket waivers (broadly applicable to all applicable providers and suppliers without making any request), (ii) provider/supplier individual requested waivers (applicable only upon a specific request that is granted to an individual provider/supplier), and (iii) state-granted waivers for Medicaid and CHIP requirements (applicable only to the state that requests the waiver - as of April 1, 2020, at least 40 states have been granted waivers). Waivers under Section 1135 of the Social Security Act typically end no later than the termination of the emergency period. The 1135 waiver authority applies only to federal requirements and does not apply to state requirements, such as state requirements for licensure or conditions of participation.

Numerous nationwide blanket waivers have been issued so far relating to Medicare, the Emergency Medical Treatment & Labor Act ("EMTALA"), the Physician Self-Referral Law ("Stark Law"), and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") requirements. A complete summary of the blanket waivers is available from CMS here. Several of these waivers are discussed below:

Stark Law Waiver:

Retroactively effective March 1, 2020, the Secretary issued nationwide blanket waivers of certain Stark Law regulations and sanctions. The Stark Law blanket waivers are available here. Notably, the remuneration and referrals described in the blanket 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 COVID19;
- 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 and some examples of their use include:

- Personally Performed Services. 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.
    - *Example*: A hospital pays physicians above their previously-contracted rate for furnishing professional services for COVID-19 patients in particularly hazardous or challenging environments.

- Payments to Physicians Below FMV.
    - 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).
        - *Example*: 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.
    - 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).
    - 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).
        - *Example*: 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.

- Payments from Physicians Below FMV.
    - 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.
        - *Example*: 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.
    - 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.
    - 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.
        - *Example*: 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.

- *Example*: 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).
- *Example*: 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 Incidental Benefits. Remuneration from a hospital to a physician in the form of medical staff incidental benefits that exceeds $36 per instance in calendar year 2020.
  - *Example*: 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.

- Nonmonetary Compensation. Remuneration from an entity to a physician (or the immediate family member of a physician) in the form of nonmonetary compensation that exceeds $423 in calendar year 2020.
  - *Example*: 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.
  - 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.
    - *Example*: 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 health records (EHR) items and services in order to continue the physician's access to patient records and ongoing EHR technology support services.
  - 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).

- Physician-Owned Hospitals.
  - 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.

        - *Example*: 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.
    - 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 certain Medicare program requirements have been met.
        - *Example*: 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 Medicare requirements of participation, in order to provide medically necessary care to patients during the COVID-19 outbreak in the United States.

- Physician-Owned Home Health Agency:
    - 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.
        - *Example*: 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.

- Location Requirements:
    - 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).
        - *Example*: 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.
    - 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.
        - *Example*: 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.

- Referrals to Family Members in Rural Areas. 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.

- *Example*: 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.

- Lack of Writing or Signature. 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.
  - *Examples* (assuming satisfaction of all requirements other than writing/signature):
    - A physician provides call coverage services to a hospital before the arrangement is documented and signed by the parties.
    - 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.
    - 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.

Although the blanket waivers may be used beginning on 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. Inquiries regarding the Stark Law blanket waivers may be sent to 1877CallCenter@cms.hhs.gov.

EMTALA Waiver:

Effective March 1, 2020, the Secretary is waiving the enforcement of section 1867(a) of the Social Security Act to allow hospitals, psychiatric hospitals, and critical access hospitals (CAHs) to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, so long as it is not inconsistent with a state's emergency preparedness or pandemic plan. A waiver of EMTALA sanctions is effective only if actions under the waiver do not discriminate as to source of payment or ability to pay.

HIPAA Waiver:

Effective March 15, 2020, the Secretary issued a limited waiver of sanctions and penalties for covered hospitals for certain HIPAA non-compliance, as discussed in our Client Alert.

Medicare Telehealth Coverage Waiver:

Starting March 6, 2020, the Secretary waived certain limitations on Medicare coverage for telehealth visits, as discussed more in our Client Alert. Medicare can now pay for telehealth furnished anywhere across the country, including in a patient's home, for both new and established patients.

Medicare Program Requirements Waivers:

Effective March 1, 2020, numerous blanket waivers have been issued for various provider types, including hospitals, psychiatric hospitals, critical access hospitals (CAHs), long-term care facilities, skilled nursing facilities (SNFs), and nursing facilities (NFs), home health agencies (HHAs), hospice, end-stage renal dialysis (ESRD) facilities, and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). In addition, certain CMS requirements for provider enrollment, licensure, and Medicare appeals have been waived. For more information regarding these blanket waivers, please see the CMS COVID-19 Toolkit, Summary, Fact Sheet, and MLN Article.

If you have questions regarding COVID-19 and compliance and enforcement, please contact a member of our Healthcare and Life Sciences Practice Group. You can also check out our COVID-19 Resources page for more information.