Blanket Waivers of Section 1877(g) of the Social Security Act Due to Declaration of COVID-19 Outbreak in the United States as a National Emergency

Effective March 1, 2020

I. Preamble

Section 1135 of the Social Security Act (the Act) authorizes the Secretary of the Department of Health and Human Services (the Secretary) to waive or modify certain Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act of 1996 requirements. Two prerequisites must be met before the Secretary may invoke the waiver authority. First, the President must have declared an emergency or disaster under either the Stafford Act or the National Emergencies Act. Second, the Secretary must have declared a Public Health Emergency under section 319 of the Public Health Service Act. As of March 13, 2020, both of these prerequisites were met.

Under section 1135 of the Act, the Secretary may grant waivers to ensure, to the maximum extent feasible, in any emergency area and during an emergency period that: (1) sufficient health care items and services are available to meet the needs of individuals in the emergency area enrolled in the Medicare, Medicaid, and CHIP programs; and (2) health care providers that furnish such items and services in good faith, but that are unable to comply with one or more requirements described in section 1135(b) of the Act, may be reimbursed for such items and services and exempted from sanctions for such noncompliance—including sanctions under section 1877(g) of the Act—absent any determination of fraud or abuse. For purposes of section 1135 of the Act, "health care providers" means any entity that furnishes health care items or services, and includes a hospital or other provider of services, a physician or other health care practitioner or professional, a health care facility, or a supplier of health care items or services.

Section 1877 of the Act, also known as the physician self-referral 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 furnished pursuant to a prohibited referral. A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity. Exceptions to the physician self-referral law are set forth in section 1877 of the Act and regulations at 42 CFR 411.355 through 411.357. Sanctions for violation of the referral and claims submission prohibitions are set forth in section 1877(g) of the Act.

This document sets forth the scope and application of the Secretary's blanket waivers of section 1877(g) of the Act as authorized under section 1135 of the Act (the "blanket waivers"). The waivers described below apply nationwide. The blanket waivers may be revised from time to time as determined necessary by the Secretary and posted on the Centers for Medicare & Medicaid Services (CMS) website. Any revisions that narrow a blanket waiver, and any termination of the blanket waivers, will be effective on a prospective basis only. CMS may issue additional blanket

waivers. Additional blanket waivers will have the effective date stated in the additional blanket waivers. For each blanket waiver, the waiver of section 1877(g) is limited to the circumstances described in the individual blanket waiver, and health care providers must satisfy all conditions of the blanket waiver in order to rely on the blanket waiver. As stated in section II.B, CMS will pay claims for designated health services that, but for satisfying the conditions of a blanket waiver, would violate the physician self-referral law.

Parties utilizing the blanket waivers must make records relating to the use of the blanket waivers available to the Secretary upon request. Although the blanket waivers may be used beginning on the effective date set forth in section II.A of this blanket waiver document and do not require the submission of specific documentation or notice to the Secretary or CMS in advance of their use, we encourage parties to develop and maintain records in a timely manner as a best practice.

Finally, we remind parties that reliance on the waivers may be unnecessary because many financial relationships related to COVID-19 Purposes (as defined in section II.A below) may satisfy the requirements of existing exceptions to the physician self-referral law.

For purposes of the blanket waivers, the following terms have the meanings set forth in 42 CFR 411.351: centralized building, designated health services, entity, fair market value, hospital, immediate family member, physician, physician in the group practice, physician organization, referral, referring physician, remuneration, rural area, and same building. For purposes of the blanket waivers, the following terms have the meanings set forth in 42 CFR 411.354: financial relationship, ownership or investment interest, and compensation arrangement.

Inquiries regarding the blanket waivers may be sent to <u>1877CallCenter@cms.hhs.gov</u>.

II. Waivers

A. Conditions Applicable to All Blanket Waivers of Section 1877(g) of the Act

The following waivers have an issuance date of March 30, 2020, but will have retroactive effect to March 1, 2020, nationwide, and shall terminate as set forth in section 1135(e) of the Act. Parties may not use the blanket waivers after the expiration of the Secretary's authority to grant waivers for the COVID-19 outbreak in the United States.

The waivers described herein apply in the geographic area covered by the President's proclamation, pursuant to the National Emergencies Act, on March 13, 2020, that the COVID-19 outbreak in the United States constitutes a national emergency; and my January 31, 2020, determination, pursuant to section 319 of the Public Health Service Act, that a public health emergency as a result of confirmed cases of 2019 Novel Coronavirus (previously referred to as 2019-nCoV, now as COVID-19), exists and has existed since January 27, 2020, nationwide.

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. Any 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. The remuneration and referrals 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 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.
- B. Blanket Waivers

Pursuant to Section 1135(b) of the Social Security Act (the Act) (42 U.S.C. § 1320b-5), I, Alex M. Azar II, Secretary of Health and Human Services, hereby waive the sanctions under section 1877(g) of the Act and regulations thereunder for referrals and claims related to the following to ensure that: (1) sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid, and CHIP programs; and (2) health care providers (as defined in section 1135(g) of the Act) that furnish such items and services in good faith, but are unable to comply with one or more of the specified requirements of section 1877 of the Act and regulations thereunder 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:

- 1. 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.
- 2. 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).
- 3. 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).

- 4. 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).
- 5. 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.
- 6. 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.
- 7. 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.
- 8. 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).
- 9. 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).
- 10. 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.
- 11. 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).
- 12. 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).

- 13. Referrals by a physician owner of a hospital that converted from a physicianowned 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.
- 14. 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.
- 15. 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).
- 16. 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.
- 17. 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.
- 18. 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.

III. Examples of Application of the Blanket Waivers

The following are examples of remuneration, referrals, or conduct that may fall within the scope of the blanket waivers set forth in section II of this blanket waiver document. These examples are for illustrative purposes only and do not represent an exhaustive list of remuneration, referrals, and claims that would qualify for the waiver of sanctions under section 1877(g) of the Act under the blanket waivers. Unless the blanket waiver expressly applies only to a specific type of entity, the examples that include a hospital would apply to any entity that furnishes designated health services.

- A hospital pays physicians above their previously-contracted rate for furnishing professional services for COVID-19 patients in particularly hazardous or challenging environments.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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).
- 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.
- 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.
- 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.
- 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.

- 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.
- 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.
- Consistent with its State's Emergency Preparedness or Pandemic Plan, a physicianowned 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.
- 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.
- 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.
- 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.
- 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.
- 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—
 - 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; 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.