

Explanatory Guidance
March 30, 2020 Blanket Waivers of Section 1877(g) of the Social Security Act

Issued April 21, 2020

I. Background

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) prohibits a physician from making a referral for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies and its requirements are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payor) for those referred DHS. A financial relationship is an ownership or investment interest in an entity that furnishes DHS or a compensation arrangement with an entity that furnishes DHS. Section 1877(g) of the Act imposes sanctions for violations of the physician self-referral law, including the denial of payment for DHS referred or billed in violation of the physician self-referral law.

On March 30, 2020, the Secretary of the Department of Health and Human Services (the Secretary) issued 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 (the blanket waivers). Information regarding the blanket waivers can be found at <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Spotlight>. These blanket waivers apply nationwide, are effective March 1, 2020, and may be used by parties without submission of specific documentation or advance notice to the Secretary or the Centers for Medicare & Medicaid Services (CMS), although records relating to the use of the blanket waivers must be made available to the Secretary upon request. Following the issuance of the blanket waivers, CMS received requests for guidance regarding the scope and application of the blanket waivers to certain financial relationships.

II. Explanatory Guidance

The following information relates to the scope and application of the blanket waivers to certain financial relationships. The terms used in this explanatory guidance document have the meanings set forth in the March 30, 2020 blanket waiver document and 42 CFR Part 411, Subpart J.

We do not restate here the blanket waivers or any of the information included in the March 30, 2020 blanket waiver document. However, we again remind parties that reliance on the blanket waivers may be unnecessary because many financial relationships and referrals related to COVID-19 Purposes (as defined in the March 30, 2020 blanket waiver document) may satisfy the requirements of existing exceptions to the physician self-referral law. The Secretary will work with the Department of Justice to address False Claims Act relator suits where parties using the blanket waivers have a good faith belief that their remuneration or referrals are covered by a blanket waiver.

A. Compliance with Non-Waived Requirements of an Applicable Exception

Certain of the blanket waivers (blanket waivers #1 through #11) relate to requirements for remuneration in exceptions for compensation arrangements at 42 CFR 411.357, while others (blanket waivers #12 through #14) relate to requirements in exceptions for ownership or investment interests at 42 CFR 411.356. Blanket waivers #15 through #17 waive the sanctions of section 1877(g) of the Act when the specified requirements of the “services” exceptions at 42 CFR 411.355 are not satisfied. Blanket waiver #18 waives the sanctions of section 1877(g) of the Act when a compensation arrangement is not set forth in writing or signed by the parties.

As stated in the March 30, 2020 blanket waiver document, the sanctions under section 1877(g) of the Act and regulations thereunder are waived for referrals and claims that would violate the physician self-referral law due to the failure of the financial relationship or referral to satisfy the specified requirements of the exceptions to the physician self-referral law. Financial relationships or referrals, as applicable, must satisfy all non-waived requirements of an applicable exception in order to avoid the referral and billing prohibitions of section 1877 of the Act. The failure of a financial relationship or specific referral to satisfy one or more of the other requirements of an applicable exception would trigger the physician self-referral law’s referral and billing prohibitions.

B. Amendment of Compensation Arrangements

Parties seeking to use the blanket waivers have inquired about their ability to modify the remuneration terms of their existing arrangements during the emergency period of the COVID-19 outbreak in the United States (the emergency period). Some parties questioned whether the remuneration terms of an existing compensation arrangement could be amended during the emergency period and then again at the conclusion of the emergency period to return to the original terms of the arrangement.

CMS has historically interpreted and continues to interpret preamble guidance in the Fiscal Year 2009 Inpatient Prospective Payment System (FY 2009 IPPS) final rule (73 FR 48434) to allow a second or subsequent amendment of the remuneration terms of a compensation arrangement, even within the first year after an initial amendment of the remuneration terms of the arrangement, provided that, each time the remuneration terms are amended, all requirements of an applicable exception are satisfied, the amended remuneration is determined before the amendment is implemented, the formula for the amended remuneration does not take into account the volume or value referrals or other business generated by the referring physician, and the overall arrangement remains in place for at least 1 year following the amendment. With respect to the use of the blanket waivers, if parties amend the remuneration terms of an existing compensation arrangement during the emergency period, the amended arrangement must satisfy all non-waived requirements of an applicable exception. Following the expiration of the emergency period, the remuneration terms of the compensation arrangement may again be modified to return to the original terms of the arrangement or to effectuate additional necessary modifications to the arrangement, provided that, each time the remuneration terms are amended, all requirements of an applicable exception are satisfied, the amended remuneration is

determined before the amendment is implemented, the formula for the amended remuneration does not take into account the volume or value referrals or other business generated by the referring physician, and the overall arrangement remains in place for at least 1 year following the amendment.

It is possible that a “modification” of an existing compensation arrangement could instead be analyzed as an additional compensation arrangement between or among the same parties during the term of the emergency period. For example, assume that a hospital leases office space to a physician and that the lease arrangement satisfies all requirements of 42 CFR 411.357(a). During the emergency period, the hospital wishes to provide financial support to the physician to assist with the physician’s practice operating costs and ensure that medical care and related services are available to patients in the community during the emergency period. Although the hospital could modify the lease arrangement to reduce the rental charges during the emergency period, it could also enter into a separate compensation arrangement with the physician to provide the financial support without changing the remuneration terms of the lease arrangement. The parties could use the blanket waivers, if necessary, to avoid sanctions under the physician self-referral law for the financial support to the physician, keeping in mind that the blanket waivers will terminate as set forth in section 1135(e) of the Act.

C. Applicability of Blanket Waivers to Indirect Compensation Arrangements

Blanket waivers #1 through #11 address remuneration between an entity and a physician or an immediate family member of a physician. One condition applicable to all of these blanket waivers is that the remuneration described in the applicable blanket waiver is 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. Parties have inquired whether the blanket waivers also apply to an indirect compensation arrangement between an entity and a physician or the immediate family member of the physician.

The blanket waivers do not apply to indirect compensation arrangements as defined at 42 CFR 411.354(c)(2). Parties may request an individual waiver of the sanctions under section 1877(g) of the Act related to remuneration that constitutes an indirect compensation arrangement under section 42 CFR 411.354(c)(2).

As a practical matter, a waiver for indirect compensation arrangements may not be necessary in most instances. Under 42 CFR 411.354(c)(3)(i), a physician who stands in the shoes of his or her physician organization (as defined at 42 CFR 411.351) is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. All physicians with non-titular ownership or investment interests stand in the shoes of their physician organizations. (See 42 CFR 411.354(c)(1)(ii) and (2)(iv)(A).) Any other physician in a physician organization is permitted to stand in the shoes of the physician organization. (See 42 CFR 411.354(c)(1)(iii) and (2)(iv)(B).) Thus, when a compensation arrangement for which parties seek protection under the blanket waivers is directly between an entity and a physician organization, the remuneration is deemed to be directly between the entity and: (1) each non-titular physician owner of the physician organization; and (2) each non-owner

physician in the physician organization whom the parties treat as permissively standing in the shoes of the organization.

D. Repayment Options for Loans between a DHS Entity and a Physician (or the Immediate Family Member of a Physician)

Blanket waivers #10 and #11 address remuneration in the form of a loan with an interest rate below fair market value or on terms that are unavailable from a lender that is not in a position to make referrals to or generate business for the party making the loan. Parties seeking to use these blanket waivers identified the exceptions for isolated transactions and fair market value compensation at 42 CFR 411.357(f) and (l), respectively, as applicable to loan arrangements between entities and physicians, and inquired whether such an arrangement must provide for repayment of the loan in cash. Some parties inquired whether a physician could repay a loan in kind through the provision of professional or other services to the entity making the loan, or whether an entity could repay a loan in kind through the provision of office space, items, or services to the physician lender. Other parties inquired whether the entity making a loan could forgive some or all of the debt if the physician who is the recipient of the loan proceeds agrees to and, in fact, does maintain a medical practice and continue to serve patients in the community where the entity is located for a predetermined period of time after receipt of the loan proceeds.

Nothing in either of the exceptions identified in the inquiries requires cash payments to satisfy a borrower's debt to a lender. However, blanket waivers #10 and #11 do not waive sanctions for referrals and claims related to the repayment of the loan. Thus, the aggregate value of in-kind payments must be consistent with the amount of the loan balance being reduced through the in-kind payments. In addition, compensation arrangements involving in-kind payments must be commercially reasonable. They may also implicate the Federal anti-kickback statute (section 1128B(b) of the Act; 42 U.S.C. § 1320a-7b(b)).

The maintenance of a medical practice and continuing to serve patients in the community where an entity is located may constitute a physician's in-kind loan repayment to the entity depending on the applicable facts and circumstances of the parties. We previously stated that a physician's *relocation* to a community to establish a medical practice is not properly viewed as a benefit to a recruiting hospital but rather as a benefit to the community. (See 69 FR 16096.) We note that the exception for retention payments in underserved areas at 42 CFR 411.357(t) may be available to protect remuneration from a hospital to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital.

E. Repayment of Loans, Rent Abatement, or Other Amounts Due Following the End of the Emergency Period

As described in section II.D, blanket waivers #10 and #11 address remuneration in the form of a loan with an interest rate below fair market value or on terms that are unavailable from a lender that is not in a position to make referrals to or generate business for the party making the loan. Several other blanket waivers address remuneration to or from an entity or physician that is below fair market value for the office space, equipment, items, or services furnished by or to the entity or physician. Parties that wish to use blanket waivers #10 or #11, as well as parties that

wish to be repaid for any reduction in rental charges or other amounts due to them under new or existing compensation arrangements, inquired about compliance with the physician self-referral law if repayment is not complete prior to the termination of the blanket waivers. The parties expressed concern that, after the termination of the blanket waivers, the compensation arrangement would no longer satisfy the requirements of an applicable exception because the interest charges, rental charges, or other charged amounts would not be consistent with the fair market value of the remuneration provided.

The completion of obligations under an arrangement after its expiration or termination is common and need not result in noncompliance with the physician self-referral law. For example, assume that a compensation arrangement calls for payment for a physician's services upon the provision of documentation that the services were furnished and the presentation of an invoice for payment. Assume also that the arrangement expired by its terms on December 31, 2019. The entity may not receive documentation of and invoices for services furnished on or before December 31, 2019 until after such date. The entity may make appropriate payments for previously furnished services after the expiration of the arrangement.

Appropriate repayment terms agreed to prior to the termination of the blanket waivers may continue beyond the termination of the blanket waivers without running afoul of the physician self-referral law. However, any disbursement of loan proceeds after the termination of the blanket waivers, or additional remuneration after the termination of the blanket waivers for office space, equipment, items, or services furnished by or to an entity or physician, must satisfy all requirements of an applicable exception.

F. Restructuring of Existing Recruitment Arrangements with Income Guarantees

Parties have inquired whether any of the blanket waivers address the extension or other restructuring of existing physician recruitment arrangements. Specifically, parties inquired whether a hospital could extend an income guarantee under an existing physician recruitment arrangement for the purpose of addressing the recruited physician's medical practice 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 exception at section 1877(e)(5) of the Act and 42 CFR 411.357(e) for physician recruitment permits certain compensation arrangements to induce a physician to relocate his or her medical practice to the geographic area served by a hospital in order to become a member of the hospital's medical staff. In our 2007 advisory opinion, CMS-AO-2007-01, we stated that parties to a recruitment arrangement should not be able to amend their arrangement after it has commenced to provide for additional (or potentially additional) compensation to the recruited physician. We concluded that, because the physician would have already relocated his or her medical practice, the additional compensation would not be for the purpose of inducing relocation and may directly or indirectly reflect the volume or value of the recruited physician's actual or potential referrals.

None of the blanket waivers change this core requirement of the exception for physician recruitment, and the analysis set forth in advisory opinion CMS-AO-2007-01 remains CMS

policy. However, other blanket waivers may be available to waive sanctions of section 1877(g) for remuneration from a hospital (or other entity) to assist a physician whose medical practice experiences 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. For example, blanket waiver #5 waives sanctions under section 1877(g) of the Act for referrals and claims related to rental charges that are below fair market value for the physician's lease of office space from an entity, and blanket waiver #10 waives sanctions under section 1877(g) of the Act for referrals and claims related to remuneration from an entity to a physician resulting from a loan to the physician with an interest rate below fair market value or on terms that are unavailable from a lender that is not a recipient of the physician's referrals or business generated by the physician.