

CMS FINALIZES TWO NEW STARK EXCEPTIONS AND PROVIDES SOME CLARITY TO OTHERS

On October 30, 2015, the Centers for Medicare and Medicaid Services (CMS) issued a [final rule](#), to be effective January 1, 2016, which added two new exceptions and made numerous clarifications to the Stark regulations.

Exception for Recruitment of Non-Physician Practitioners (NPPs)

Currently, a facility's ability to provide financial assistance for the purpose of recruiting and relocating practitioners to the facility's geographic service area is limited to physicians. In the final rule, CMS articulates a need for a new exception for NPPs due to the projection of a significant shortage in primary care providers. As a result, the new exception will allow hospitals, federally qualified health centers (FQHC) and rural health clinics (RHC) to make payments to physicians to assist in recruiting, employing and contracting NPPs to work in the geographic area served by the facility.

Most of the requirements of the new exception track the requirements of the existing physician recruitment exception, but it is important to highlight three key elements. First, an NPP does not qualify for the exception if the NPP practiced in the geographic area served by the hospital, FQHC or RHC in the year preceding his or her employment by the physician. Second, for purposes of the exception, NPPs include physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, clinical social workers and clinical psychologists. And, third, the NPP must be providing primary care or mental health services to patients of the physician's practice and be a bona fide employee of the physician receiving the remuneration from the hospital, FQHC or RHC. Primary care services include general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology.

Exception for Timeshare Arrangements

The second new Stark exception enables timeshare arrangements. These arrangements permit a licensee to use the premises, equipment, personnel, items, supplies and/or services of the licensor entity (i) without establishing a possessory leasehold interest as is required under the existing lease exception and (ii) without requiring a block lease arrangement set in advance, as is also

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required under the existing lease exception. These timeshare arrangements can be on an “as needed” basis so long as the compensation is time-based and not in any way related to the amount or value of services provided during the timeshare or referred between the parties.

This exception is welcomed because previously these “timeshare arrangements” may not have qualified for protection under a combination of the existing Stark exceptions for leasing space, equipment, and personal services. Furthermore, CMS notes that it does not intend for this exception to adversely affect any other arrangements that are similar to timeshare arrangements but comply with an existing Stark exception.

In order for a timeshare arrangement to fit within the new exception, the following requirements must be met:

- The arrangement must be set forth in advance, in a signed writing identifying the premises, items, equipment, supplies, and services covered.
- The arrangement must be between a physician (or a physician organization in whose shoes the physician stands) and a hospital or physician organization of which the physician is not an owner, employee or contractor.
- The premises, items, supplies, and services must be used predominantly for the provision of evaluation and management services to patients and on the same schedule (note: CMS commentary does not provide any additional guidance on this “on the same schedule” requirement).
- If any equipment is covered in the timeshare arrangement, it must be located in the same building as where the evaluation and management services are provided.
- The equipment must not be used to furnish any other designated health services other than those that are incidental to the evaluation and management services. Equipment cannot include advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment.
- The arrangement cannot be conditioned on the referral of patients by the physician-licensee to the hospital or physician practice-licensor.
- The compensation for the term of the arrangement must be set in advance, consistent with fair market value, and not take into account volume or value of referrals or other business generated between the parties. Compensation cannot be based on (1) a percentage of the revenue raised, earned, billed, collected or otherwise attributable to the services provided using the timeshare space, or (2) on a per-unit of service fees that are not time based.
- The arrangement must be commercially reasonable even if no referrals were made between the parties.
- The arrangement must not convey a possessory leasehold interest in the office space that is the subject of the arrangement.
- The arrangement must not otherwise violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission.

Additional Clarifications

In addition to adding the exceptions described above, CMS also finalized numerous clarifying points to the Stark regulations. These clarifications include, but are not limited to:

- **Writing Requirement.** In a move that gives greater flexibility to providers, CMS clarifies that there is no Stark requirement that an arrangement must be recorded in a single formal contract to satisfy that an arrangement is “in writing.” Instead,

the writing can be a collection of contemporaneous documents. These documents may include board meeting minutes, written communication between parties (including e-mails) fee schedules for certain specified services, check requests or invoices, time sheets which show the services performed, call coverage schedules, accounts payable or accounts receivable documents, and any checks that were issued for items, services, or rent. Additionally, CMS clarifies that each document does not need the signatures of one or both parties to be compliant with the “in writing” requirement. But, more importantly, one document in the arrangement must have the signature of each party and each such document must reference the other documents comprising the arrangement. The takeaway for providers is that while one document signed by all parties remains preferable, multiple documents may satisfy a Stark requirement that the arrangement be “in writing” provided, however, this collection of documents must allow for a “reasonable” person to verify compliance with the applicable Stark exception.

• **Holdover Arrangements.** Previously, holdover arrangements for expired leases of space, equipment or services were limited to six months. Now, so long as the original arrangement was Stark compliant and contained a holdover provision, the holdover arrangement can continue indefinitely on the same terms as the original arrangement, even without a new writing. Providers must be aware of two other considerations relating to this change. First, providers relying on holdover provisions must have contemporaneous documents establishing that the holdover arrangement continued on the same terms and conditions as the original arrangement. And, second, providers must be aware of the possibility that, after a period of time, the original payments may no longer be fair market value and thus a new arrangement may be required.

• **Lease Term.** Multiple Stark exceptions require that the arrangement have a term of at least one year. CMS now makes clear that a relationship that lasts, as a practical matter, for at least one year satisfies this requirement. The exact term of the arrangement does not need to be included in the formal document so long as the arrangement actually continues for one year, or terminates during the first year without the parties entering into a new arrangement for the same space, equipment or services during that year, and the parties have contemporaneous documents to establish such.

• **Compliance with Signature Requirements.** Compliance with signature requirements for compensation arrangements will now be considered to be met so long as the parties obtain the required signatures within ninety (90) consecutive calendar days following the date the arrangement became noncompliant. Currently, there are different time frames depending on whether noncompliance is inadvertent or advertent.

If you have any questions regarding Stark in general or any of the items discussed in this article, please contact Paul E. Knag at 203.653.5407 or pknag@murthalaw.com, Stephanie Sprague Sobkowiak at 203.772.7782 or ssobkowiak@murthalaw.com or Daniel J. Kagan at 203.772.7726 or dkagan@murthalaw.com.