The Stark Law has been updated effective January 1, 2016 in ways that may affect your medical practice and hospital relationships. Among other things, these updates add two new exceptions to the referral prohibition, relax certain technical requirements, and offer several clarifications.

**Timeshare Arrangements Exception**

The first new exception is the timeshare arrangements exception. This new exception explicitly permits timeshare arrangements for the use of office space, equipment, personnel, items, supplies, and other services. Previously, these timeshare arrangements had to fall within the existing rental of office space exception, which requires exclusive use of the space during the time of the lease. This requirement was inherently challenging for some timeshare arrangements to meet. The new timeshare exception permits physicians to use premises, equipment, personnel, items, supplies or services on a limited or as needed basis. The key conditions of the timeshare arrangements exception include that:

- The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services covered by the arrangement.
- The arrangement is between a physician and a hospital or physician organization of which the physician is not an owner, employee, or contractor.
- The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used predominantly for the provision of evaluation and management services and on the same schedule as those services.
- The equipment covered by the arrangement is located in the same building where evaluation and management services are furnished, not used to furnish designated health services other than those incidental to the evaluation and management services furnished at the time of the patient’s evaluation and management visit; and not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (CLIA waived laboratory tests are excluded).
- The arrangement is not conditioned on the referral of patients by the physician who is a party to the arrangement to the hospital or physician organization of which the physician is not an owner.
- The arrangement is commercially reasonable and the compensation to be paid under the arrangement is set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals, a formula based on percentage of revenues, or a formula based on per-unit of service fees that are not time-based.

\(^1\) As part of the 2016 Medicare Physician Fee Schedule, CMS released final revisions to the Stark Law, such revisions are located at 80 Fed. Reg. 70886, 71300 (Nov. 16, 2015).
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Relaxed Technical Requirements

The recent updates also relaxed some of the strict technical requirements under the Stark Law. The relaxed requirements are aimed at reducing the number of self-disclosures submitted to CMS, particularly for violations of the statute that are unlikely to increase the risk of federal program abuse. The relaxed requirements include the following:

- Arrangements as a whole must be evidenced in writing, but not in one written contract. Instead, an arrangement can be evidenced by a collection of documents and still satisfy the writing requirements.
- Arrangements need not explicitly state that the term is for at least one year. Parties can show compliance with the one-year term requirement with multiple documents that establish the relationship lasted for over a year.
- CMS extended the “holdover” period for the space and equipment rental exceptions, and personal services arrangements exception, from six months to an indefinite time period as long as the arrangement continues on the same terms and conditions as the original agreement.
- Parties have a 90-day grace period to obtain a missing signature, regardless of whether the failure was inadvertent. However, the exception may only be used once every three years for the same referring physician.

Although the regulations have relaxed some of the strict technical drafting requirements in arrangements, providers still need to be diligent when drafting and entering into arrangements that implicate the Stark Law.

Nonphysician Practitioner Assistance Exception

The second new exception is the assistance to compensate nonphysician practitioners (“NPP”) exception, which applies to the recruitment and retention of NPPs, such as physician assistants and nurse practitioners. The NPP assistance exception, if satisfied, permits hospitals, federally qualified health centers, and rural health clinics to provide financial assistance to physicians to assist in the bona fide employment of, or contracting with, an NPP by that physician to provide primary care and mental health services to patients of the physician practice. The requirements of this new exception are similar to those of the existing physician recruitment exception; however, some of the requirements of the new exception that stand out include the following:

- The arrangement is set out in writing and signed by the hospital, the physician, and the NPP.
- Substantially all (which is defined as at least 75%) of the services provided by the NPP must be primary care or mental health services.
- A hospital can provide up to 50% of the actual aggregate compensation, signing bonus, and benefits paid to the NPP who joins the practice. Total compensation cannot exceed fair market value.
- Assistance cannot be provided for more than two consecutive years.
- The NPP has not within one year of commencement of the compensation arrangement with the physician: (1) practiced in the geographic area served by the hospital; and (2) been employed or otherwise engaged to provide patient care services by a physician or physician organization that has a medical practice in the geographic area served by the hospital, even if such services were never provided.
- The exception can only be utilized by a hospital, federally qualified health center, or rural health clinic once every three years with respect to a single referring physician.
Clarifications

Lastly, a few definitions were clarified under the new regulations:

- Clarifying changes have been made to multiple exceptions to make clear that all compensation exceptions that refer to the value or volume of referrals are to be analyzed under the same standard, making the use of the phrase “takes into account” uniform across all of the compensation exceptions that include a value or volume standard.

- The definition of remuneration now excludes items, devices and supplies used solely for collecting, transporting, processing, and storing specimens, ordering tests or procedures, and communicating the results of tests for the entity furnishing the items, devices or supplies. It was also clarified that unless a hospital bills for services globally, a physician’s use of hospital resources when treating hospital patients does not qualify as remuneration.

- The new rule clarifies that as to the “stand in the shoes” provision all physicians in a physician organization are considered parties to the compensation arrangement between an organization and a designated health services entity, except for purposes of the signature requirement.

The Stark Law is a strict liability statute, and providers must remain vigilant to ensure compliance with Stark Law regulations or risk substantial penalties and repayment obligations. If you have questions about any of the Stark Law updates, or general compliance concerns, please contact Erin Aebel at 813.227.2357 or at eaebel@slk-law.com, Rachel Goodman at 813.227.2328 or at rgoodman@slk-law.com, or Kelly Thompson at 813.676.7281 or at kthompson@slk-law.com. Shumaker, Loop & Kendrick, LLP has one of the largest health law practices in Florida with nine health lawyers. The health law group is co-administered by Ronald Christaldi and Erin Aebel, board certified health lawyers. The firm has more than 30 other Florida lawyers who also serve clients in the health care industry.