On October 30, 2015, the Centers for Medicare and Medicaid Services (CMS) issued a final rule (the "Final Rule"), which was published in the Federal Register on November 16, 2015, that resulted in the first major changes to the Physician Self-Referral Law (the "Stark Law") since 2009. The changes are designed to help the Stark Law accommodate health care delivery and payment system reform, and reduce burdens on health care entities and physicians to comply with the various technical requirements of the Stark Law. The Final Rule will take effect on January 1, 2016.

The Stark Law 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 an exception applies. The Final Rule establishes two new exceptions to the Stark Law and also clarifies certain technical requirements needed to satisfy various existing exceptions to the Stark Law. Some of the important Stark Law changes under the Final Rule are summarized below.

**New Exceptions to Stark Law**

In an effort to expand access to primary care and mental health services, the Final Rule established an exception for remuneration made by a hospital, federally qualified health center (FQHC) or rural health clinic (RHC) to a physician (or physician organization) to assist the physician in recruiting a nonphysician practitioner in the geographic area served by the hospital, FQHC or RHC. To satisfy this new exception, an arrangement must comply with the following key elements, among others:

- Substantially all of the services furnished by the nonphysician practitioner to patients of the physician’s practice must be primary care services or mental health care services;
- The remuneration to the physician by the hospital, FQHC or RHC must not exceed 50% of the actual compensation, signing bonus and benefits paid by the physician to the nonphysician practitioner;
- The remuneration to the physician can only be paid for the initial two consecutive years of the compensation arrangement between the physician and the nonphysician practitioner;
• The nonphysician practitioner must not have practiced in the geographic region served by the relevant hospital, FQHC or RHC within one year of the commencement of his or her compensation arrangement with the physician.

The Internal Revenue Service (IRS) has not provided a formal view on subsidies paid by a tax exempt hospital, FQHC and RHC to a physician for the recruitment of a nonphysician practitioner, and tax exempt health providers should consult with tax counsel when evaluating what affect paying such subsidies may have on their tax exempt status.

The Final Rule also established an exception to the Stark Law for timeshare arrangements that involve a physician’s use of another person or entity’s premises, equipment, personnel, items, supplies or services. In developing this new exception, CMS recognized that physicians oftentimes require space, equipment or services to treat patients for legitimate reasons without requiring a traditional lease arrangement. The new exception for timeshare arrangements will allow physicians to use another’s space and equipment on a limited or as-needed basis without having to satisfy the various requirements under the current office or equipment lease exceptions to the Stark Law, which require, among other things, that a physician use the space or equipment exclusively during the leased period. For this new exception to apply, an arrangement must comply with the following key elements, among others:

• The arrangement must be between a physician and a hospital or physician organization of which the physician is not an owner, employee or contractor;

• The items covered by the arrangement must be used predominantly for the provision of health evaluation and management services to patients; and

• The arrangement cannot cover the physician’s use of advanced imaging equipment, radiation therapy equipment or clinical or pathology laboratory equipment.

Clarification of Requirements Under Existing Exceptions

In addition to establishing the two new exceptions noted above, the Final Rule clarified certain technical requirements under existing exceptions to the Stark Law. First, CMS clarified that the exceptions to the Stark Law requiring that an arrangement be “in writing” (such as the office lease exception and the personal services exception, among others) do not require that the arrangement be documented in a single written contract. Rather, CMS made clear that arrangements may satisfy the “in writing” requirement if memorialized through a collection of documents that evidence the course of conduct between the parties.

CMS also clarified that the exceptions to the Stark Law requiring that an arrangement have a term of at least one year (including the office lease exception, equipment lease exception and personal services exception) do not require a contract with an explicit provision identifying the one-year term. Rather, an arrangement may satisfy the one-year term requirement if the arrangement actually lasts for one year as a matter of fact.

The Final Rule also modified the current exception to the Stark Law that allows for holdovers of a previously compliant arrangement. Currently, the holdover exception permits compliant arrangements of at least one year to continue for a period of six months after the arrangement’s stated expiration date as long as the arrangement continues on the same terms and conditions. As modified, the exception will allow for holdovers that exceed six months (and will also allow for indefinite holdovers),
provided that certain additional safeguards are met. In order to satisfy the modified holdover exception, an arrangement must continue to satisfy an applicable exception to the Stark Law for the entire holdover period.

With respect to those exceptions to the Stark Law that require a signature between the parties to an arrangement, the Final Rule clarified the amount of time that the parties have to comply with the signature requirement once the arrangement takes effect. Under the current rule, parties must obtain a missing signature within 30 days after the arrangement takes effect if the failure to obtain the signature is advertent, and 90 days after the arrangement takes effect if the failure to obtain the signature is inadvertent. The Final Rule eliminated the distinction between an advertent and inadvertent failure to obtain a signature, and provided that in all cases the parties have 90 days after an arrangement takes effect to comply with the signature requirement.

**Implications and Take Away**

Beginning when the Final Rule takes effect on January 1, 2016, health care entities and physicians will be able to take advantage of the two new exceptions to the Stark Law. In particular, the new exception for timeshare arrangements will prove useful to physicians who desire to utilize office space, equipment and personnel on a part-time basis without establishing an additional medical practice location.

Health care entities should also find compliance with the Stark Law less burdensome once the Final Rule takes effect, as CMS’s clarification of certain technical requirements under existing exceptions to the Stark Law provide those that are subject to the law with more flexibility in establishing compliant arrangements. CMS’s clarifications also suggest that violation of the technical requirements of the Stark Law may be a lower enforcement priority for CMS than violation of the more substantive requirements. An important question implicated by the Final Rule is how CMS will treat arrangements that violated the Stark Law prior to the effective date of the Final Rule but now satisfy one of the new exceptions to the law. Another question is how CMS will treat the failure to comply with the newly clarified technical requirements of the Stark Law prior to the effective date of the Final Rule. While many believe that CMS’s clarifications to the technical requirements of the Stark Law will be applied retroactively, CMS’s application of the Final Rule over the coming months should be monitored. Relevant parties should also evaluate whether the new exceptions to the Stark Law and CMS’s clarifications of the current regulations implicate any of their current arrangements—as the Final Rule may indicate that an existing arrangement satisfies an exception to the Stark Law that otherwise may have been non-compliant.

While the Final Rule evidences CMS’s continued effort to keep the Stark Law up to date with the reality of modern healthcare delivery systems, some may feel that there are still many more changes to the Stark Law that need to be made to ensure that the law does not impede legitimate arrangements with physicians that may improve access to care. For example, CMS could consider removing the signature requirement under various exceptions to the Stark Law altogether, or changing the Stark Law from a strict liability statute to one that takes into account the intent of the parties when assessing the legitimacy of an arrangement. Nevertheless, the Final Rule suggests that CMS will continue to assess the elements of the Stark Law and its various exceptions on an ongoing basis, and hopefully continue to eliminate unnecessary compliance burdens as it balances between the need to prevent Medicare program abuse and allow health care providers to arrange for better and broader delivery of health care.
If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers:

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