Significant Stark Law Changes in 2016 Medicare Physician Fee Schedule Intended to Ease Compliance Burden

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On October 30, 2015, the Centers for Medicare & Medicaid Services ("CMS") released the final 2016 Medicare Physician Fee Schedule (the "Final Rule") which contains, among other things, significant changes to the Physician Self-Referral Rule (the "Stark Law"). The Stark Law changes in the Final Rule are little changed from the proposed rule that was released in July, 2015. The Final Rule was published in the Federal Register on November 16, 2015, and will take effect on January 1, 2016.

The Stark Law generally prohibits a physician from referring Medicare and Medicaid patients to hospitals, labs and other providers with which the physician has a financial relationship, unless an exception applies. According to CMS, the Stark Law changes are intended to accommodate health care delivery and payment system reform, reduce burdens, facilitate compliance with technical requirements, and issue new exceptions to the Stark prohibitions.

The Final Rule includes two new exceptions, and various clarifications and revisions to existing policies, definitions and exceptions. Some of the more important Stark Law changes are summarized below.

**NEW EXCEPTIONS**

**Assistance to Compensate Nonphysician Practitioner.** In an effort to increase access to quality care, the Final Rule creates an exception for recruitment assistance and retention payments made by a hospital, federally qualified health center ("FQHC") or rural health clinic ("RHC") (collectively "Provider"), to physicians to recruit and hire non-physician practitioners ("NPP"). This exception may only be used once every three years. The subsidiary may not exceed 50 percent of the actual compensation (including signing bonus and benefits) paid during the first two years of employment. Additionally, within one year of the commencement of this employment, the non-physician may not have (i) practiced in the "geographic area" served by the Provider or (ii) been employed by a physician or physician organization with a medical
practice located in the "geographic area." Substantially all of the services provided by the NPP must be for primary care services or mental health care services.

**Timeshare Arrangements.** The Final Rule also creates an exception to the Stark Law for timeshare arrangements that involve the use by a physician of another person’s or entity’s premises, equipment, personnel, items, supplies or services. The new exception allows use of space and equipment on a limited or as-needed basis without requiring a traditional lease arrangement. However, for the exception to apply, an arrangement must comply with certain requirements including, among others: (i) the arrangement must be in writing, signed and specifies what is used; (ii) the arrangement must be between a physician and a hospital or physician organization in which the physician is not an owner, employee or contractor; (iii) the items covered by the arrangement must be used predominantly for the provision of health evaluation and management ("E&M") services to patients; (iv) the equipment must be located in the same building where the E&M are furnished and the equipment must not be used to furnish health services other than those incident to the E&M services; (v) the arrangement must not cover the physician’s use of advanced imaging equipment, radiation therapy equipment or clinical or pathology laboratory equipment; (vi) the arrangement must not be conditioned upon referral of patients; (vii) the compensation must be set in advance and consistent with fair market value ("FMV"); (viii) the arrangement must be commercially reasonable; and (iv) the arrangement must not convey a possessory leasehold interest in the office space that is subject to the arrangement.

**REVISIONS TO EXISTING POLICIES, DEFINITIONS AND EXCEPTIONS**

**Written Arrangements.** The Final Rule clarifies that exceptions to the Stark Law that require an arrangement to be in writing do not require a single written contract. Although CMS recommends a single written contract for arrangements, the “in writing” requirement may be satisfied through a collection of documents that relate to one another and set forth the course of conduct between the parties. The collection of documents to make a writing could include: board meeting minutes or other documents authorizing payments for specified services; written communication between the parties, including hard copy and electronic communication; fee schedules for specified services; check requests or invoices identifying items or services provided, relevant dates, and/or rates of compensation; time sheets documenting services performed; call coverage schedules or similar documents providing dates of services to be provided; accounts payable or receivable records documenting the date and rate of payment and the reason for payment; and checks issued for items, services, or rent.

**One Year Requirement.** The Final Rule clarifies that the Stark Law exceptions that require arrangements to have a term of at least one year (including the exceptions for office space rental, equipment rental and personal service arrangements), do not require a contract provision specifically identifying a one-year term. Rather, the one-year duration requirement can be satisfied if the arrangement, in fact, lasts for one year.

**Signature Requirement.** Certain exceptions to the Stark Law require a signature. Currently, parties must remedy the signature requirement within 30 days after the arrangement went into effect if the failure to obtain the signature was inadvertent, and 90 days if the failure was inadvertent. The Final Rule clarifies that there is a 90-day remedial period regardless of whether the failure was inadvertent or not. The parties do not
need to sign a single formal written contract to meet the signature requirement. A signature is required on a contemporaneous writing documenting the arrangement. Perhaps a signature on a check or on a purchase order may be enough.

**Indefinite Holdover.** Currently, expired arrangements under the office space and equipment rental exceptions and personal services arrangements exceptions can be “held over” for a period of six months after the arrangement’s stated expiration date. Under the Final Rule, expired arrangements can be held over indefinitely, provided the arrangement: (i) satisfies all of the requirements at the time of expiration; (ii) continues on the same terms and conditions; and (iii) continues to satisfy all of the requirements during the holdover.

**Definition of Remuneration.** CMS amended the language defining “remuneration” to not include the furnishing of items, devices and supplies if used exclusively for one or more of the following six purposes: collection, transportation, processing, storing, ordering or communicating the specimen/results. The revision clarifies that the item can be used for more than one of these six purposes as long as it is used solely for one or more of those purposes.

**CONCLUSION**

The Stark Law changes in the Final Rule are extensive and we have touched upon a few of the important ones here. Generally, once the Final Rule takes effect on January 1, 2016, Stark Law compliance should be a bit less burdensome, and health care entities will benefit from being able to take advantage of the two new exceptions.

If you have any questions regarding these changes, including steps that should be taken to both comply with and take advantage of the amended rules, please contact Gary J. McRay or Nicole E. Stratton.