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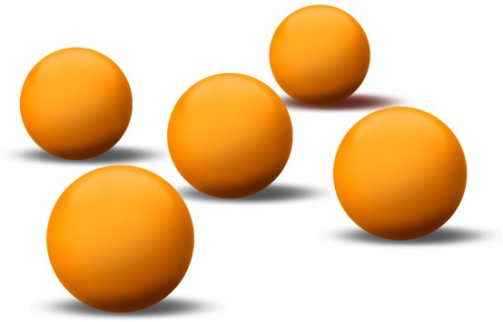
Recent Changes to the Stark Law Provide Added Flexibility



By Kelli Carpenter Fleming

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The 2016 Medicare Physician Fee Schedule Final Rule ("Final Rule") contains recent changes to the Federal Stark Law, the majority of which took effect on January 1, 2016. The issuance of the Final Rule on November 16, 2015 was the first time the industry has seen such broad changes to the physician self-referral law in several years. According to CMS, the changes are designed to "accommodate delivery and payment system reform, to reduce burden, and to facilitate compliance." While a summary of all the recent changes is beyond the scope of this article, I did want to highlight some of the more significant changes.

By way of background, the Stark Law prohibits a physician from referring Medicare or Medicaid patients for certain "designated health services" to entities with which the physician (or an immediate family member of the physician) has a financial relationship, unless an exception applies. Any relationship in which remuneration (*i.e.*, something of value) flows between the parties is considered a financial relationship under the Stark Law. Designated health services ("DHS") covered by the Stark Law include the following: (1) clinical laboratory services; (2) physical therapy, occupational therapy, and outpatient speech language pathology services; (3) radiology and certain other imaging services; (4) radiation therapy services and supplies; (5) durable medical equipment and supplies; (6) parenteral and enteral nutrients, equipment and supplies; (7) prosthetics, orthotics and prosthetic devices and supplies; (8) home health services; (9) outpatient prescription drugs; and (10) inpatient and outpatient hospital services. The majority of the Final Rule changes address the exceptions to the Stark Law—in other words, the instances in which CMS has stated that a financial relationship is permitted between referring parties.

In the Final Rule, CMS establishes two new Stark Law exceptions. The first exception permits hospitals, federally qualified health centers, or rural health clinics to provide assistance to physicians to recruit and compensate non-physician practitioners (*i.e.*, nurse practitioners, clinical nurse specialists, physician assistants, certified nurse midwives, clinical social works, and clinical psychologists) under certain conditions (which are similar to the conditions under the exception for physician recruitment). At least 75% of the patient care services provided by the recruited non-physician practitioner must be primary care or mental health services. Further, the payment to the physician cannot exceed 50% of the aggregate compensation, signing bonus, and benefits paid to the non-physician practitioner and must be consistent with fair market value. This new exception can only be utilized once every three years for a particular physician (unless the practitioner leaves prior to the expiration of one year) and there is a two-year limit on the assistance provided.

The second new exception permits time-share arrangements for the use of office space, equipment, personnel, items, supplies, and services. The exception applies to arrangements that grant a right of permission to use the premises, equipment, personnel, items, supplies, or services, but not to arrangements that transfer control over such items. While these types of arrangements have been in place for years and have been analyzed under other Stark Law exceptions, the new exception provides clarification and flexibility. There are some limitations, however, to the use of the new exception. For

example, advance imaging equipment (*e.g.*, MRI and CT) and clinical or pathology laboratory equipment may not be used within the shared space. Further, compensation formulas based on revenue percentage or per-unit fees are prohibited.

CMS also made several clarifications to existing Stark Law exceptions in the Final Rule. While a discussion of all of the clarifications is beyond the scope of this article, I did want to highlight a few.

- Many Stark Law exceptions contain a requirement that the arrangement be "in writing". In the Final Rule, CMS clarified that the "writing" does not necessarily need to be a single written contract, but rather can be a collection of contemporaneous writings that relate to each other and that document the relationship (*e.g.,* e-mails, invoices, check requests, board meeting minutes, time sheets, etc.). A document produced after a referral is made, however, cannot be used to demonstrate compliance with respect to prior referrals. Nonetheless, a single written contract remains the recommended method of documentation when possible.

- For exceptions requiring a one-year arrangement, CMS clarified that the one-year term does not have to be expressed in the writing, provided the parties can show factual compliance with the one-year requirement through other documentation.

- Previously, under the exception for leases and personal services agreements, a holdover period at the expiration of the agreement was limited to six (6) months. The Final Rule allows for an indefinite holdover period on the same terms as the original agreement as long as the arrangement remains compliant with the applicable exception. Amendments during the holdover period are prohibited. It is recommended that the parties review holdover agreements periodically to confirm that the arrangement remains compliant.

- Under the previous provisions, if a signature to an arrangement was missing, the parties had thirty (30) days to obtain the missing signature if the omission was not inadvertent and ninety (90) if the omission was inadvertent. Under the Final Rule, parties now have ninety (90) days to obtain a missing signature regardless of whether the omission was inadvertent.

- CMS clarified that when parties split-bill for services (*e.g.,* hospital bills technical component and physician bills professional component), this alone does not create a financial relationship between the parties.

- The Final Rule clarifies that the definition of remuneration under the Stark Law does not include the provision of items, devices, or supplies that are used solely to collect, transport, process or store specimens or to order or communicate the results of tests or procedures.

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