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Practice Group:

Health Care

Potential Stark Changes Ahead

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On July 15, 2015, the Centers for Medicare and Medicaid Services ("CMS") published proposed regulations governing policies and payments made under the Physician Fee Schedule for calendar year 2016 (the "Proposed Rule").[1] In response to the numerous Self-Referral Disclosure Protocol ("SRDP") submissions by healthcare providers, CMS has proposed clarifying guidance and significant amendments to the regulations implementing the federal physician self-referral law ("Stark Law"), including two new exceptions and revisions to regulatory definitions. In general, the proposed revisions indicate that CMS is seeking input into ways to offer healthcare providers additional flexibility under the Stark Law, particularly with regard to several technical requirements under the law. CMS is accepting public comments on the Proposed Rule until September 8, 2015.

Proposed Changes to the Stark Law

New Stark Law Exceptions

Recruitment Exception Related to Nonphysician Practitioners. CMS acknowledges the increasing need for primary care nonphysician providers, particularly in remote and underserved areas, due to changes in healthcare delivery and payment systems, the expansion of healthcare coverage access, and growth of the aging population. Accordingly, CMS has proposed revising Stark Law regulations to add a new exception that permits remuneration from a hospital, federally qualified health center ("FQHC") or rural health clinic ("RHC") to a physician or physician organization for the purposes of recruiting certain primary care nonphysician practitioners into the geographic area served by the hospital, FQHC, or RHC. This proposed exception requires, among other factors, that the nonphysician practitioner be a *bona fide* employee of the physician or practice, and be employed for the purpose of proving primary care services. Additionally, CMS has proposed a cap on both the amount of remuneration that a hospital, FQHC, or RHC can provide the physician or physician organization, as well as the length of the assistance period.

Timeshare Arrangement Exception. In the Proposed Rule, CMS notes that certain timeshare arrangements are structured more as a license to use office space, property and personnel of the licensor and may not meet the Rental of Office Space Exception,[2] which requires the arrangement to provide for the exclusive use of the premises, and a term of at least one year. As such, CMS proposes to add a new exception that would protect timeshare arrangements meeting certain criteria, including several elements that are reminiscent of those in the Rental of Office Space Exception, but tailored to the unique nature of a timeshare arrangement. The new exception would only be available to arrangements

[1] Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 41686 (proposed July 15, 2015) (to be codified at 42 C.F.R. pts. 405, 410, 411, 414, *et al*.).

[2] 42 C.F.R. § 411.357(a).

between a hospital or physician organization as the licensor and a physician as the licensee, and only to the extent that the physician licensee is primarily providing evaluation and management services to patients. Additionally, under the Proposed Rule, any equipment covered by the arrangement must be located in the office suite where the physician performs evaluation and management services and may not be used to furnish DHS other than DHS which is incidental to the physician's evaluation and management services and furnished at the time of such services. The equipment may not include any advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests). Finally, the compensation methodology under the timeshare arrangement may be based on an hourly, daily or other time-based basis, but may not be based on certain other per unit of service or percentage-based methodologies.

Revisions Offering Providers Additional Flexibility with Stark Law Compliance

CMS proposes many changes which, if finalized, will reduce the regulatory burdens on healthcare providers and provide additional guidance. These include:

Writing Requirement. In order to provide uniformity and clarity, CMS proposes to remove terms such as "agreement" and "written contract" in several Stark law regulatory exceptions and replace such phrases with the term "arrangement." By proposing to revise the regulations in this manner, CMS acknowledges that there is no requirement in the Stark Law that an arrangement be documented solely as a single, formal contract and that various types of "writings" evidencing the parties' course of conduct may satisfy the relevant requirements. If finalized, such revision will grant healthcare providers additional flexibility in complying with the writing requirements.

Term Requirement. CMS clarifies that the one-year term requirement in the Rental of Office Space Exception, Rental of Equipment Exception,[3] and Personal Services Exception[4] does not require a written contract containing a formalized term provision. Rather, parties must be able to demonstrate with available contemporaneous documentation that "as a matter of fact," the arrangement under these exceptions lasted for at least one year, or that the arrangement was terminated during the first year and the parties did not enter into a similar arrangement in accordance with regulatory requirements.

Holdover Arrangements. CMS proposes two alternate revisions to the 6-month holdover provision in the exceptions for lease arrangements for the Rental of Office Space Exception, Rental of Equipment Exception, and Personal Services Exception: (i) indefinite holdovers, subject to certain safeguards, or (ii) holdovers for certain, definite periods of time, such as a 1-, 2-, or 3-year holdover period or the time period equivalent to the term of the preceding arrangement. A revision under either alternative will likely afford healthcare providers additional flexibility with regard to "expired" agreements under which the parties continued to operate under the same terms and conditions of the prior arrangements. CMS has also proposed to amend the Fair Market Value Exception[5] to permit arrangements of any timeframe (including those for greater than one year) to be renewed for any number of times, provided the arrangement continues to satisfy all other requirements of the exception.

[3] 42 C.F.R. § 411.357(b).
[4] 42 C.F.R. § 411.357(d).
[5] 42 C.F.R. § 411.357(l).

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Temporary Non-Compliance with Signature Requirements. CMS proposes modifications to the special rule on temporary non-compliance with signature requirements for compensation arrangements. Currently, if an arrangement is temporarily out of compliance with the signature requirement but otherwise fully satisfies the requirements of the applicable exception, the entity may obtain necessary signatures within 90 days if the failure to comply is inadvertent or within 30 days if the failure to comply is not inadvertent. Under the Proposed Rule, CMS proposes to allow an entity 90 days to obtain required signatures, regardless of whether the non-compliance is inadvertent.

Revisions to Stark Law Definitions and Other Clarifying Changes

Remuneration. The current Stark Law regulations exclude from the definition of "remuneration" the provision of items, devices or supplies that are used solely to collect, transport, process, or store specimens for the entity providing the items, devices or supplies in order to communicate the results of the tests or procedures for such entity.[6] The Proposed Rule proposes to revise the definition to clarify that the phrase "used solely" would mean that the item, device or supply may be used for one *or more* of the six permissible purposes, but it cannot be used for any purpose outside of the six purposes listed in the statute. CMS also clarifies that, despite a Third Circuit ruling[7] to the contrary, it does not consider an arrangement between a physician and a hospital in which the hospital and physician separately bill to constitute remuneration.

Stand in the Shoes. Stark Law regulations provide that a physician with an ownership or investment interest in a physician organization "stands in the shoes" of that organization for purposes of applying the rules regarding direct and indirect compensation arrangements. CMS previously took the position that only non-titular physician owners and those physicians who volunteer to stand in the shoes are deemed parties to an agreement between a physician organization and a DHS entity. In the Proposed Rule, CMS proposes to amend the "stand in the shoes" provision in order to clarify that, for all elements *except* the signature requirements, all physicians in a physician organization are considered parties to a compensation arrangement between a physician organization and DHS entity when analyzing the requirements of an applicable exception. Although additional CMS guidance will be helpful in applying this new definition, it appears that CMS does not intend to redefine "physician organization," or redefine which physicians stand in the shoes, but rather CMS is intending that if any physician stands in the shoes, CMS will require all physicians related to the physician organization be included in the determination of whether an arrangement meets the elements of an applicable exception.

Physician-Owned Hospital Ownership Interests. CMS proposes to revise the regulations regarding the calculation of ownership or investement interests in a physician-owned hospital, specifically to require that the investment level include interests held by both referring and non-referring physicians. Investment levels are measured as of March 23, 2010. CMS guidance previously referenced the definition of ownership or investment interest in another part of the Stark regulations, which only includes interests of referring physicians.

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[6] 42 C.F.R. § 411.351.

[7] *See United States ex rel. Kosenske v. Carlisle HMA*, 554 F.3d 88 (3d Cir. 2009) (concluding that a physician's use of a hospital's resources such as the facility, equipment, nursing personnel, and supplies when treating a hospital patient constitutes remuneration, even if the hospital bills separately for the resources and services it provides and the physician bills only for professional fees).

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The Proposed Rule modifies the prior policy by establishing a new definition of "ownership or investment interest" that only applies to the physician-owned hospital interests. The proposed definition does not differentiate between ownership or investment interests held by referring and non-referring physicians. The Proposed Rule also clarifies that ownership interests should be calculated to include ownership interests held by a physician who no longer practices medicine, as long as the physician fits within the regulatory definition of "physician." Finally, CMS proposes to change public disclosure requirements for physician-owned hospitals, providing more clarity regarding the language that constitutes a sufficient statement of physician ownership or investment, and the types of communication that require a disclosure.

Geographic Area Served By FQHCs and RHCs. CMS recognizes that the current definition of "geographic area served by the hospital" in the Stark Law physician recruitment exception, which is contingent on the volume of hospital inpatients, has little applicability to FQHCs and RHCs. Therefore, CMS proposes two alternative methods to define the geographic area served by an FQHC or RHC: (i) the area composed of the lowest number of contiguous zip codes from which it draws at least 90 percent of its patients on an encounter basis (which is closely aligned with the existing rule for rural hospitals), and (ii) the area composed of the lowest number of contiguous and noncontiguous zip codes from which it draws at least 90 percent of its patients on an encounter basis.

"Takes into Account" Terminology. For the sake of consistency, CMS proposes to revise the language related to the volume or value standard in several of the Stark Law regulatory exceptions so that the standards will be applied uniformly.

Retention Payments in Underserved Areas. In the Proposed Rule, CMS explains that it intended the regulatory language in the exception for retention payments to physicians in underserved areas to exactly mirror the Phase III preamble language, which provided that a retention payment to a physician may not exceed the lower of: (1) an amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months); or (2) the reasonable costs the hospital would otherwise expend to recruit a new physician into the hospital's geographic area. The current regulatory language current states, in relevant part, "measured over no more than a 24-month period," and therefore, CMS has proposed to amend the regulatory text to reflect the original regulatory intent that the entire 24-month period be averaged.

Publicly Traded Securities Exception. The Proposed Rule attempts to modernize the exception for ownership of publicly traded securities by updating the security exchanges that qualify a security ownership for the exception.

Locum Tenens Physician. CMS proposes to delete the reference to "stand in the shoes" from the regulation's definition of "locum tenens," so as to not be confused with the term as referenced in other parts of the Stark law.

Solicitation for Comments

CMS solicits comments regarding all of the proposed modifications outlined herein. Quite notably, CMS specifically requested commentary regarding the Stark Law's impact on health care delivery and payment reform, and the perceived need for regulatory revisions regarding permissible physician compensation. CMS acknowledges that since the Stark Law has been enacted and implemented, there have been significant changes in the delivery of health care

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services and the payment for such services. The Proposed Rule highlights the fact that evolving health care delivery and payment models focus on clinical and financial integration among a variety of healthcare providers in order to achieve the goals of improving access to quality, affordable health care services. It is evident that CMS is examining the Stark Law's impact on clinical and financial integration, alternative payment systems and the practicalities associated with the future landscape of healthcare.

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