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ALERT

Health Care

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CMS Proposes New Stark Exceptions and Clarifications in Proposed 2016 Physician Fee Schedule Rule

On July 8, 2015, the Centers for Medicare and Medicaid Services ("CMS") released its proposed Calendar Year ("CY") 2016 Physician Fee Schedule ("PFS") Proposed Rule, which was published in the Federal Register on July 15, 2015.

In response to CMS's experience with disclosures made under its Voluntary Self-Referral Disclosure Protocol, the proposed rule, if finalized as proposed, would clarify a number of knotty and persistent interpretive dilemmas in the application of key terms and requirements in the physician self-referral ("Stark Law") regulations – including whether a single, integrated and formal contract is required to satisfy the "writing" requirement present in multiple Stark exceptions. The proposed rule would also add two important new exceptions and make other technical revisions that provide welcome flexibility in the Stark Law regime. In sum, the proposed rule reflects a newly flexible and pragmatic approach by CMS in Stark Law enforcement, one that seems designed to alleviate the burden on not just providers but CMS itself in navigating this notoriously rigid strict-liability statute.

Clarification of Key Regulatory Terms and Requirements

- Writing, Term and Missing Signature Requirements: According to CMS, the requirement of many Stark Law exceptions (including those for realty and equipment leases, personal service arrangements and fair market and indirect compensation) for a "writing" or "written agreement" need not be satisfied by evidence of a single formal contract. Instead, depending on the facts and circumstances, a collection of contemporaneous documents, including documents evidencing the course of the parties' conduct, may suffice. CMS also proposes to clarify that Stark exceptions conditioned on a term of at least one year do not require a formal written contract or other document with an explicit provision identifying the term of the arrangement. Rather, an arrangement that lasts at least one year satisfies this requirement.
- Failure to Obtain Required Signatures: CMS proposes to allow parties 90 days to obtain required signatures to an agreement, irrespective of whether the failure to secure a timely signature is knowing or inadvertent. At present, the temporary non-compliance grace period for a late signature lapses after 30 days when the parties are aware that the signature is missing.
- Holdover Arrangements: CMS proposes to eliminate the time limitations on holdover arrangements to allow for indefinite holdovers or, alternatively, to extend the permitted holdover period to some definite period longer than the current six months. As is the case presently, to be eligible for continuing Stark Law compliance, holdovers would be required to continue on the same terms and conditions as the original compliant arrangement and to stipulate payment that remains fair market value throughout the holdover period.
- Physician-Owned Hospitals: CMS proposes to limit the categories of websites and the forms of advertising that require disclosure that a hospital has physician ownership, and to clarify the variety and simplicity of disclosure statements that would be sufficient for a hospital to comply. CMS also proposes to require that, when calculating their baseline and prospective levels of physician investment, hospitals include all owners who are physicians, whether or not they are referring physicians at the time. While the industry generally would welcome implementation of the changes that govern website and advertising disclosures, hospitals that have relied on CMS's prior guidance to disregard ownership by non-referring physicians may find that the new rules, if adopted, would challenge the compliance of their current equity structures. CMS sought commentary as to the implementation period for changes in this category, if the changes are finalized.

Establishes a New Exception for Timeshare Leases

Recognizing the variety of legitimate reasons that may drive a physician away from a traditional office space lease arrangement, CMS proposes to establish a new exception for qualifying timeshare arrangements between physicians and hospitals. To qualify under the proposed exception, (i) a licensee would be required to use the licensed premises, equipment, personnel, items, supplies and services predominantly to furnish evaluation and management services to patients of the licensee, and (ii) the arrangement could not involve advanced imaging equipment, radiation therapy equipment or clinical or pathology laboratory equipment. The exception would be limited to timeshare arrangements in which hospitals and physician organizations are the licensors. It would not protect timeshare arrangements offered by other types of health care organizations, including independent diagnostic testing facilities and clinical laboratories.

CMS would require that license fees under part-time arrangements be determined in a time-based manner, and not consider the number of patients seen or the amount of revenue raised, earned, billed, collected or otherwise attributable to the services provided by the licensee. The proposed exception would not be available to protect part-time and exclusive leases of office space, which would continue to be measured under the long-standing exception for real property leases.

Establishes a New Exception for Assistance to Employ Non-Physician Practitioners

In response to changes in health care delivery and payment systems, and trends in primary care workforce projections, CMS proposes to establish a new exception to the Stark Law for payments made by a hospital, Federally Qualified Health Center ("FQHC") or Rural Health Center ("RHC") to a physician to assist the physician in employing a non-physician practitioner in the donor's geographic service area. For these purposes, "non-physician practitioners" would include physician assistants, nurse practitioners, clinical nurse specialists and certified nurse midwives. The proposed exception would apply only to situations in which the non-physician practitioner is a *bona fide* employee of the physician or physician practice receiving the support, and the purpose of the employment is to provide primary care services to patients of the physician practice. As proposed, the exception includes a cap on the amount of remuneration and a two-year limit on assistance. In other regards, the proposed exception tracks requirements of the existing physician recruitment exception.

Other Technical Clarifications and Revisions

In addition to the changes described above, CMS has proposed a number of other technical clarifications and revisions to the Stark regulations. These include a revised definition of "remuneration" (to reverse the decision of the Third Circuit in *United States ex rel. Kosenske v. Carlisle HMA*); harmonization of the phrase "takes into account" across Stark exceptions; changes of less than crystal clarity to the stand-in-the-shoes rules; the method for determining the geographic area served for purposes of the Stark Law's FQHC and RHC exception; and modernization of the exception for publicly traded securities.

Collectively, the proposed changes portend a substantial reduction in some of the most administratively prescriptive requirements of the Stark Law, upon whose shoals many have foundered, resulting in both voluntary repayments and self-disclosures. As CMS suggested in its preamble, the agency's practical experience garnered through the Self-Referral Disclosure Protocol—a process that, though lengthy, has offered substantial relief for technical violations, and is thus an increasingly attractive avenue for reducing Stark Law penalties—is evident in the proposed rule.

Should you have questions regarding the immediate implications of this proposed rule, including its implications for those facing potential violations that the rule, if adopted, might eliminate, please contact your usual Ropes & Gray advisor.