

PUBLICATION

Stark Regulations: 2016 Proposed Physician Fee Schedule [Ober|Kaler]

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The proposed Physician Fee Schedule for CY 2016 includes multiple technical revisions to the regulations implementing the Stark law. These revisions appear to be designed to provide greater clarity and flexibility with respect to the burden of certain technical requirements. The revisions would clarify the requirements for written agreements under certain exceptions, extend holdover provisions, create a new time share lease exception and update certain definitions. CMS believes that these changes will not create any greater risk of fraud or abuse and will hopefully reduce the number of self-disclosures of conduct that is otherwise substantively compliant with Stark requirements.

Writing, Term, and Holdover

CMS notes that under the Self-Referral Disclosure Protocol (SRDP), it frequently receives disclosures arising out of noncompliance with the statutory and regulatory provisions in the Stark law related to the requirements for written agreements. CMS seeks to clarify these requirements and provide policy guidance on their implementation. The proposed regulations would offer substantial relief to providers whose agreements contain technical, but not substantive, insufficiencies under the Stark law. Despite CMS's apparent willingness to provide greater flexibility, providers of designated health services should continue to vigilantly monitor the terms of financial arrangements involving physicians to ensure that the appropriate requirements are met and properly documented.

Writings

Under many of the statutory and regulatory exceptions to the Stark law, but most particularly those applicable to leases of space and equipment and to agreements for personal services, there has been a long-standing question as to whether the requirement for a writing requires that the arrangements be memorialized in a single, written agreement or whether a collection of documents describing the arrangement could satisfy the criteria of the applicable Stark exception. CMS clarifies in the proposed rule that the *arrangement* between the parties, which CMS describes as the "underlying financial relationship," should be sufficiently documented to demonstrate compliance with the applicable exception. "Depending on the facts and circumstances of the arrangement and the available documentation," CMS writes, a collection of documents could suffice to satisfy the writing requirement. CMS goes on to state "there is no substantive difference among the writing requirements of the various compensation exceptions that require a writing."

To further clarify this point, CMS proposes several changes to the language of the regulatory requirements by substituting "arrangement" for "agreement" and "contract" where those terms appear in compensation exceptions. The only exceptions requiring writings that remain untouched in this regard are (1) the exception for group practice arrangements with hospitals (42 C.F.R. § 411.357(h)) because it is rarely used and (2) the exceptions for electronic prescribing and electronic health records (42 C.F.R. § 411.357(v) and (w)) because they are written to mirror the antikickback safe harbor language. But, CMS notes, it believes the same general principles (requiring documentation of the underlying arrangement rather than a single written agreement) apply.

Term

CMS also proposes to clarify the documentation requirement for Stark exceptions that require a term of at least a year, including leases for space and equipment and personal services agreements. The proposed rule would codify that arrangements that do, in fact, last for at least a year, whether or not the arrangement contains a term of at least a year, should be considered to meet the one-year requirement. Such arrangements will be afforded protection under the exception provided contemporaneous writings establish that the arrangement (1) lasted for at least a year, or (2) the parties terminated the arrangement during the first year and did not enter into a similar arrangement for the same equipment, space, or services for the remainder of the first year. Again calling for an examination of the particular facts and circumstances of the situation, CMS proposes to remove references to an "agreement" in 42 C.F.R. §§ 411.357 (a)(2) and (b)(3) and to revise the first sentence of each to mirror the requirement for a one year "arrangement" set forth in section (d)(1)(iv) of the same regulation.

Holdover

CMS proposes to revise the current requirements at 42 C.F. R. §§ 411.357(a), (b), and (d) that allow parties to continue to adhere to, or "hold over," the terms of a Stark-compliant space lease, equipment lease, or personal services arrangement for a period of six months after the expiration of the arrangement, provided that the terms of the arrangement remain the same and continue to comply with the applicable Stark exception.

Citing many disclosures relating to otherwise-compliant arrangements that exceeded the holdover requirement, CMS proposed allowing infinite holdovers (or, alternately, holdovers of a period greater than 6 months) provided that the arrangement continues on the same terms as the original arrangement and that it continues to comply with the requirements (including fair market value requirements) of any applicable exception. Any changes to the terms would require a new arrangement meeting the one-year term requirement and other criteria of the applicable exception. Any noncompliance with the terms of a Stark exception (for example, a lease whose value fell below the fair market value of the space) would require a disclosure and repayment. All applicable requirements regarding written arrangements would continue to apply during the holdover.

In addition, CMS proposes to clarify the fair market value exception at 42 C.F. R. § 411.357(l)(2) to allow arrangements of any length to be renewed any number of times so long as the terms and conditions do not change. As currently worded, the fair market value exception appears to allow unlimited renewals for arrangements that are less than one year, but not arrangements that are greater than one year.

Definitions

CMS also provides clarification and updates to the definitions of several key terms:

- *Remuneration.* Without making changes to the text of the definition, CMS clarifies that for purposes of the exception to the definition of *remuneration* for items, devices, and supplies "used solely" to collect, transport, process, or store specimens, or to order tests or communicate results, using an item, device, or supply for two or more of the purposes listed in the exception does not constitute remuneration, but using such an item for an unlisted purpose does constitute remuneration.

In addition, CMS clarifies that so-called "split bill" arrangements where a physician provides services in a hospital-based department and bills Medicare for professional fees only while the hospital bills for facility fees does not constitute remuneration, but a global billing arrangement with a non-Medicare payor where both professional and facility fees were billed together would do so. This clarification responds to commentary by the Third Circuit in *U.S. ex rel Kosenske v. Carlisle HMA*, 554 F.3d 88 (3d Cir. 2009) that called into question whether "split bill" arrangements created compensation arrangements for purposes of Stark.

- *Stand in the Shoes.* CMS clarifies that, for purposes of the signature requirements of various Stark exceptions, only those physicians who are owners and investors (not employees or independent contractors) of a physician organization "stand in the shoes" of the organization. However, for other considerations, such as whether an arrangement takes the volume or value of referrals into account, all physicians associated with the organization, whether as owners, employees, or independent contractors, stand in the organization's shoes. CMS notes that without this understanding, many applicable requirements could be circumvented.
- *Locum tenens.* CMS proposes modifying the definition of "locum tenens" to remove the phrase "stand in the shoes." The reference to "stand in the shoes" in the definition of "locum tenens" is unrelated to the use of the phrase in the context of compensation arrangements.

Exception for Ownership of Publicly Traded Securities

The Stark law has long included an exception for ownership of publicly traded securities. In light of changes in the ways that securities are traded, CMS is proposing to update the exceptions. The exception would apply to trades on electronic stock markets or OTC quotation systems, so long as the systems are "standardized and publicly transparent." Trades of unlisted stock or that involve decentralized dealer networks will not qualify for protection under the exception. CMS seeks additional comments on whether fewer, different, or additional restrictions are necessary.

New Exception: Timeshare Agreements

Earlier iterations of Stark regulations have addressed so-called "turnkey" lease arrangements that allow physicians to lease not only office space but also equipment, furnishings, waiting areas, and necessary support staff for defined time intervals. In doing so, CMS had declined to allow such arrangements to be considered under the fair market value exception at 42 C.F.R. § 411.357(l), requiring instead that they comply with the exception for space and equipment leases. Under the new rule, CMS proposes a new exception to be codified at 42 C.F.R. § 411.357(y) that would allow physicians to enter into turnkey "license" agreements with hospitals and physician organizations. These arrangements would differ from traditional leases in that the licensee (the physician) would not control the space; that right would remain with the licensor. Such arrangements, CMS contemplates, would be useful to relocating physicians establishing a new practice or to physicians wishing to provide services in rural or underserved areas (though this is not a requirement for the exception).

Specifically, CMS proposes the following requirements for such arrangements:

1. The arrangement must be written and signed by the parties.
2. The arrangement must specify the space, equipment, personnel, items, supplies, and services covered.
3. The arrangement must be between a physician (as licensee) and either a hospital or a physician organization as licensor.
4. The licensed space must be used primarily for evaluation and management services to patients of the licensee.
5. Any licensed equipment must be located within the office suite, used to provide services incidental to the physician's evaluation and management services, and may not be advanced imaging, radiation therapy, or clinical or pathological laboratory equipment (except those items used to provide tests under a CLIA waiver).
6. The arrangement may not be conditioned on referrals to the licensor.

7. Compensation over the term of the license must be set in advance and must not take into account the volume or value of referrals or other business between the parties.
8. The compensation must be commercially reasonable even in the absence of referrals between the parties.
9. The arrangement does not violate the antikickback statute or any other federal or state law regarding billing or claims submission.

CMS also notes that per-use or percentage compensation arrangements would be inappropriate under the new exception and seeks comments on this point. CMS does not specify that the license be for a minimum or maximum number of intervals or the time for any particular interval, such as might otherwise be required under a block lease.

Temporary Noncompliance with Signature Requirements

CMS proposes to allow parties 90 days to obtain all required signatures on required documents and to update various other exceptions to reflect the extended timeline. The proposal would eliminate the current distinction in the regulation between "inadvertent" and "not inadvertent." CMS recognizes that it can often take 90 days to obtain necessary signatures.

This article is part of Ober|Kaler's client alert "[CMS Drives Change in Quality, Physician Payment, and Stark in Proposed 2016 Physician Fee Schedule](#)." View other installments of the alert at these links:

- [Changes Are Afoot for Quality Measures and Physician Payment Provisions](#)
- [Stark Regulations: Proposed Physician Recruitment Provisions](#)
- [Stark Regulations: Proposed Physician-owned Hospitals Provisions](#)
- [Stark Regulations: 2016 Proposed Physician Fee Schedule](#)
- [Proposed 2016 Physician Fee Schedule Would Impact Medicare Shared Savings Program](#)