CMS proposes significant changes to Stark regulations

DENTONS

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As part of its annual proposed Medicare Part B physician fee schedule rulemaking (**Proposed Rule**), which is expected to be published in the Federal Register on July 15, 2015, the US Centers for Medicare and Medicaid Services (“CMS”) is proposing a substantial number of significant changes to, and clarifications of, the regulations implementing the federal physician self referral law (Stark Law). Among the most notable are the following:

New Exception - Assistance to Employ a Nonphysician Practitioner

In light of "[s]ignificant changes in our health care delivery and payment systems, as well as alarming trends in the primary care workforce shortage projections," CMS proposes a new regulatory exception that would permit hospitals, FQHCs, and RHCs to provide remuneration to a physician or physician group to assist with the employment of certain nonphysician practitioners (specifically, physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives). In order to qualify for the proposed exception, the arrangement must meet a substantial number of requirements, including limits on the amount of remuneration that may be furnished and the length of time for which such remuneration may be provided.

New Exception - Timeshare Arrangements

According to CMS, under so-called "timeshare arrangements," a hospital or practice group will make available to a visiting independent physician the "space, equipment and services necessary to treat patients." Under such arrangements, the physician "does not need to make any improvements to the space or to bring any medical or office supplies in order to begin seeing patients." Often, "a timeshare arrangement does not transfer dominion and control over the premises, equipment, personnel, items, supplies, and services of the licensor to the licensee, but rather confers a privilege (or license) to use (during specified periods of time) the premises, equipment, personnel, items, supplies, and services that are the subject of the license."

Because such arrangements may not qualify for protection under any combination of existing Stark Law exceptions (such as those for space, equipment and personal services) -- and because such arrangements often are " necessary to ensure adequate access to needed specialty care (especially in rural and underserved areas)" -- CMS proposes a new exception to protect such arrangements. Among other things, in order to be protected under the new exception (1) the arrangement would have to be set out in writing, signed by the parties, and specify the premises, equipment, personnel, items, supplies and services covered by the arrangement, (2) the "licensed premises, equipment, personnel, items, supplies, and services [would have to be] used predominantly to furnish evaluation and management services to patients of the licensee," (3) the arrangement could not be "conditioned on the licensee’s

referral of patients to the licensor," and (4) the compensation over the term of the arrangement would have to be "set in advance, consistent with fair market value, and not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties."

"Agreement" v. "Writing"

Some Stark Law regulatory exceptions require that the parties have an "agreement" while others simply require that the parties' arrangement be in "writing." In the preamble to the Proposed Rule, CMS states that "[b]roadly speaking…there is no substantive difference among the writing requirements of the various compensation exceptions that require a writing" and, "[t]o emphasize the uniformity of the writing requirement in the compensation exceptions," CMS proposes to remove the term "agreement" from virtually every exception in which it appears. CMS emphasizes that "the revised rules would still require a writing," but not any "particular kind of writing," such as "a formal contract." For example, "[d]epending on the facts and circumstances of the arrangement and the available documentation, a collection of …contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the…exceptions that require that an arrangement be set out in writing."

Holdover Arrangements

Several Stark Law regulatory exceptions permit a “holdover” arrangement for up to six months if (1) an arrangement of at least one year expires, (2) the arrangement satisfies the requirements of the exception when it expires, and (3) the arrangement continues on the same terms and conditions after its stated expiration. These exceptions would be amended (1) "to permit indefinite holdovers under certain conditions," or (2) "[i]n the alternative…to extend the holdover for a definite period (for example, a 1-, 2-, or 3-year holdover period) or for a period of time equivalent to the term of the immediately preceding arrangement (for example, a 2-year lease would be considered renewed for a new 2-year period)."

Temporary Noncompliance with Signature Requirements

Under the current Stark Law regulations, if the failure to comply with the signature requirement of an exception is "inadvertent," the parties must obtain the required signature(s) within 90 days; otherwise, the parties must obtain the required signature(s) within 30 days. Recognizing that "it is not uncommon for parties who are aware of a missing signature to take up to 90 days to obtain all required signatures," CMS is "proposing to modify the current regulation to allow parties 90 days to obtain the required signatures, regardless of whether or not the failure to obtain the signature(s) was inadvertent."

One-Year Term

Many Stark Law regulatory exceptions require that the arrangement at issue have a term of at least one year. According to CMS, some stakeholders have concluded that "a formal written contract or other document with an explicit provision identifying the term of the arrangement is necessary to satisfy the 1-year term requirement of the exceptions." In the preamble to the Proposed Rule, CMS states that "[a]n arrangement that lasts as a matter of fact for at least 1 year satisfies this requirement" and a "formal contract or other document with an explicit 'term' provision is generally not necessary to satisfy this element of the exception."

Takes into Account

Many Stark Law regulatory exceptions have so-called "volume or value" requirements. In some cases, the requirement is that the compensation at issue cannot "take into account" the volume or value of physician referrals. In other cases, however, the exception provides that the compensation cannot be "based on," or must be "without regard to," the volume or value of physician referrals. "[C]oncerned that the use of different phrases pertaining to the volume or value of referrals…may cause some to conclude incorrectly that there are different volume or value standards in the compensation exceptions," the Proposed Rule would amend the Stark Law regulations to uniformly utilize the "take into account" language.

"Stand in the Shoes"

In the preamble to the Proposed Rule, CMS states that it considers "a physician who is standing in the shoes of his or her physician organization to have satisfied the signature requirement of an applicable exception when the authorized signatory of the physician organization has signed the writing evidencing the arrangement." The agency remains concerned, however, "about the referrals of all physicians who are part of a physician organization that has a compensation arrangement with a DHS entity when we analyze whether the compensation between the DHS entity and the physician organization takes into account the volume or value of referrals or other business generated between the parties." According to CMS, if it "did not consider the referrals of all the physicians in the physician organization, and instead only considered the referrals of those physicians who stand in the shoes of the physician organization, DHS entities would be permitted to establish compensation methodologies that take into account the volume or value of referrals or other business generated by non-owner physicians in a physician organization when entering into a compensation arrangement with the physician organization."

Accordingly, CMS proposes to clarify that "for all purposes other than the signature requirements, all physicians in a physician organization are considered parties to the compensation arrangement between the physician organization and the DHS entity." (Presumably, what the agency means is not that non-physician owners will stand in the shoes of the physician organization at issue, but rather that the referrals of such physicians may be relevant to determining whether the direct compensation arrangement between a physician-owner and DHS entity qualify for protection under a Stark Law regulatory exception.)

Kosenske

In the preamble to the Proposed Rule, CMS notes that in United States ex rel. Kosenske v. Carlisle HMA, 554 F.3d 88 (3d Cir. 2009), "the Third Circuit Court of Appeals held that a physician's use of a hospital's resources (for example, examination rooms, nursing personnel, and supplies) when treating hospital patients constitutes remuneration under the physician self-referral law, even when the hospital bills the appropriate payor for the resources and services it provides (including the examination room and other facility services, nursing and other personnel, and supplies) and the physician bills the payor for his or her professional fees only." According to the agency, it does "not believe that such an arrangement involves remuneration between the parties, because the physician and the DHS entity do not provide items, services, or other benefits to one another. Rather, the physician provides services to the patient and bills the payor for his or her services, and the DHS entity provides its resources and services to the patient and bills the payor for the resources and services. There is no remuneration between the parties for purposes of the Stark Law."

Stark Law and Value-Based Purchasing

In the Proposed Rule, CMS solicits comments on a wide range of topics relating to the same basic dilemma: how to implement a 25 year-old law that is built to address abuses arising in a predominantly fee-for-service world when both government and commercial payers are rapidly transitioning to some variation on value-based purchasing. According to the agency, "[s]takeholders have expressed concern that," with a few, narrow exceptions, "the physician self-referral law prohibits financial relationships necessary to achieve the clinical and financial integration required for successful health care delivery and payment reform." In an effort to address this, the Proposed Rule solicits comments "regarding perceived barriers to achieving clinical and financial integration posed by the physician self-referral law generally and, in particular, the 'volume or value' and 'other business generated' standards set out in our regulations."

Your Key Contacts

Ramy Fayed
Partner, Washington, DC
D +1 202 408 6193
ramy.fayed@dentons.com

Christopher G. Janney
Partner, Washington, DC
D +1 202 408 9151
christopher.janney@dentons.com

Gadi Weinreich
Partner, Washington, DC
D +1 202 408 9166
M +1 301 325 5385
gadi.weinreich@dentons.com