

CMS Proposes Stark Law Modifications, Including Two New Exceptions

On July 8, 2015, the Centers for Medicare & Medicaid Services (“CMS”) released its annual proposed rule for the CY 2016 Medicare Part B Physician Fee Schedule (“Proposed Rule”). The Proposed Rule, which is scheduled to be published in the Federal Register on July 15, 2015, clarifies certain regulatory terminology; provides guidance on CMS’s interpretation of the Prohibition on Certain Physician Self-Referrals, known as the “Stark Law”; and establishes two new exceptions to the Stark Law. Overall, the proposed modifications appear to provide several potentially positive changes for health care providers. In addition to providing needed clarification to the existing Stark Law, the proposed modifications have the potential to significantly reduce the burden of technical violations experienced by many providers. The two new exceptions would promote arrangements that could bring additional primary care and specialty service providers to rural areas.

Below is a brief summary of the modifications proposed by CMS.

New Exceptions

Recruitment of Non-Physician Practitioners. CMS proposes a new, limited exception to assist rural entities, including hospitals, Federally Qualified Health Centers (FQHCs), and Rural Health Clinics (RHCs), to recruit non-physician practitioners. This new exception would permit hospitals, FQHCs, and RHCs to provide remuneration to a physician or physician group to assist of the entities to recruit certain non-physician 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:

- (i) limits on the amount of remuneration that may be furnished and the length of time for which such remuneration may be provided;
- (ii) the non-physician practitioner must be a *bona fide employee*; and
- (iii) the purpose of the employment is to provide “primary care services” to patients of the physician practice.

For purposes of this new proposed exception, “primary care services” includes general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology services. CMS is soliciting comments as to whether this exception should also apply to non-physician practitioners who are recruited as independent contractors.

Timeshare Arrangements. CMS proposes a new exception to protect certain timeshare leases under which a hospital or practice group will make available to a visiting independent physician the “space, equipment and services necessary to treat patients.” CMS acknowledges that these arrangements are very common, particularly in rural areas, and may not qualify for protection under existing Stark Law exceptions. To fit within the proposed exception, the arrangement must meet the following criteria:

- (1) the arrangement must be set out in writing and signed by the parties;

- (2) the arrangement specifies the premises, equipment, personnel, items, supplies and services covered by the arrangement;
- (3) the arrangement is between a hospital or physician organization (the licensors) and a physician (the licensee) for use of the hospital/physician organization's premises and other equipment and personnel;
- (4) the licensed premises are used primarily for the evaluation and management of the licensee's patients;
- (5) the equipment in the space also meets certain criteria (and cannot be advanced imaging, radiation therapy or clinical/pathology laboratory equipment);
- (6) the arrangement is not conditioned on referrals;
- (7) the compensation is set in advance, is consistent with fair market value and does not take into account the volume or value of referrals;
- (8) the arrangement is commercially reasonable; and
- (9) the arrangement does not violate the Anti-Kickback Statute or other state or federal laws or regulations governing billing or claims submission.

General Proposed Revisions

Definition of Remuneration. The Stark definition of "remuneration" excludes 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, or to order or communicate the results of tests or procedures for such entity." CMS proposes to clarify this definition to state that the item must be used solely for *one or more* of the aforementioned purposes, and for no other purpose not enumerated in the statute.

Writing Requirement. CMS clarified that there is no requirement that lease or personal services arrangements be documented in a *single, formal contract*; a collection of documents may be satisfactory, depending on the particular facts and circumstances of an arrangement. To this end, CMS proposes to substitute the term "arrangement" in exchange for "agreement" or "contract" in several Stark exceptions, including Rental of Office Space, Rental of Equipment and Physician Recruitment.

Term Requirement. Certain Stark Law exceptions require that the arrangement have a term of at least one year. CMS clarified that an agreement with an explicit 'term' provision is generally not required to satisfy the one-year term requirement. The requirement is satisfied so long as the arrangement, as a matter of fact, lasts for at least one year, or the arrangement was terminated during the first year and the parties did not enter into a new arrangement for the same services.

Temporary Noncompliance with Signature Requirements. CMS proposes to amend the special rule regarding temporary noncompliance with signature requirements to allow the parties up to ninety (90) days to obtain all required signatures, regardless of whether the late signature is advertent or inadvertent.

“*Takes into Account*”. Many compensation exceptions to Stark prohibit compensation that “takes into account” referrals or contain similarly prohibitions. CMS proposes to clarify these prohibitions by amending the Physician Recruitment, Medical Staff Incidental Benefits, and Obstetrical Malpractice and Professional Courtesy exceptions so that all of the compensation exceptions will be consistent and use the exact phrase “takes into account” rather than similarly worded prohibitions. CMS clarified that it was never its intent that these exceptions be viewed as having distinguishable standards for the consideration of the volume or value of referrals.

Ownership of Publicly Traded Securities. CMS proposes modifications and is seeking comment regarding the qualifications for a security to be deemed “publicly traded.” CMS proposes to include securities listed for trading on an electronic stock market or OTC quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.

Health Systems / Physician Practices

Holdover Provisions. Several exceptions, including Rental of Office Space, Rental of Equipment and Personal Service Arrangement exceptions, currently permit a “holdover” arrangement for up to six (6) months if certain criteria are met. CMS proposes to amend these holdover provisions to permit either *indefinite* holdovers or holdover extensions for longer, definite periods of time (*e.g.*, one year, three years, etc.), provided that certain safeguards are met. The Fair Market Value Compensation exception would also be revised to permit renewals of arrangements of any length of time.

“*Stand in the Shoes*”. The concept of physicians who “stand in the shoes” of their physician organization is relevant for purposes of determining compliance with certain exceptions, most notably determining the parties to an arrangement. Generally, only physician owners and those who volunteer to stand in the shoes are deemed to be the parties. When applying the exceptions for arrangements with physicians who stand in the shoes of their physician organization, CMS has clarified that the signature requirement is met when the arrangement is signed by the physician organization or any physician who stands in the shoes. However, with respect to applying all other requirements of the exceptions, including relevant referrals, CMS proposed that *all* physicians are deemed parties to the arrangement (including employees and independent contractors).

“*Incident To*”. CMS proposes to revise the requirements under which physicians or other practitioners can bill for incident to services. The modification would require that the physician or practitioner who bills for the incident to services must also be the physician who *directly supervises* the auxiliary personnel who provide the incident to services. Additionally, if the auxiliary personnel have been excluded from a federal health care program, the incident to services cannot be billed.

Access to Care and Value-Based Developments

Geographic Area Served by FQHCs and RHCs. The Physician Recruitment exception permits FQHCs and RHCs to make recruitment payments to physicians in the same manner as hospitals. However, the current definition of “geographic area served by a hospital” depends upon the hospital’s inpatient volumes, a criterion that has little applicability to FQHCs and RHCs.

Therefore, CMS proposes two alternatives for adding a new definition of "geographic area" for those areas served by a FQHC or RHC. The proposed methods involve calculations of either:

- (i) contiguous, or
- (ii) contiguous and noncontiguous zip codes from which the FQHC/RHC draws at least ninety-percent (90%) of its patients.

Retention Payments in Underserved Areas. CMS noted that the Phase III preamble language differed from language published in the corresponding regulations. The preamble states that a retention payment based on a physician's certification may not exceed the lower of the following: (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 have to expend to recruit a new physician to the geographic area. The regulations state that the income should be "measured over no more than a 24-month period," which can be interpreted differently than intended. Because the preamble language more accurately reflects CMS's intent, CMS proposes to modify the regulations so that they mirror the preamble language.

Physician-Owned Hospitals. CMS proposes changes to ownership and public advertising requirements under the exception relating to physician ownership and investment in hospitals. CMS proposes to revise the requirement that the baseline *bona fide* investment level and the *bona fide* investment level include direct and indirect ownership and investment interests held by a physician, regardless of whether the physician refers patients to the hospital. Further, the direct or indirect ownership interests held by an individual who no longer practices medicine would be counted if he or she satisfies the definition of "physician". In addition, CMS proposes to provide physician-owned hospitals more certainty regarding the forms of communication that require a disclosure statement, and the types of language that would constitute a sufficient statement of physician ownership or investment.

Finally, CMS is soliciting comments on a number of the proposed modifications. Specifically, CMS asks for comments related to:

- (i) perceived barriers in achieving clinical and financial integration posed caused by the "volume or value" and "other business generated" standards set out in the Stark Law regulations;
- (ii) whether health care providers and other industry stakeholders would appreciate guidance from CMS on the application of the regulations as they relate to physician compensation that is unrelated to participation in alternative payment models; and
- (iii) the impact of proposed regulatory and policy revisions on physician-owned hospitals, and on the measures or actions physician-owned hospitals would need to undertake to come into compliance with proposed revisions.

Comments on the Proposed Rule are due to CMS no later than 5:00 pm on Sept. 8 and may be submitted electronically, via mail or by hand delivery.

If you have questions about the proposed changes discussed above, or would like to submit comments to CMS, please contact any of the following attorneys: Rachael Ream, Sandy Johnson, Barbra Nault, Stephen Rose.