

CMS ISSUES SWEEPING PROPOSED RULE WITH MANY STARK LAW MODIFICATIONS

OVERVIEW

On July 8, 2015, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule pertaining to payment policies under the Physician Fee Schedule for CY 2016 ("Proposed Rule").¹ In addition to changes to the Physician Fee Schedule and other Medicare Part B payment policies, the Proposed Rule also addressed many potential modifications to the Stark Law, including the creation of new exceptions and guidance on CMS's interpretation of existing Stark Law exceptions. The Proposed Rule, if implemented as currently proposed, would update the Stark Law regulations to account for recent changes relating to health care reform and advancements in patient care and payment methodologies.

This article is intended to briefly summarize the proposed changes that affect arrangements impacted by the Stark Law. Hall Render will soon be publishing additional detailed analyses of these and other modifications addressed by the Proposed Rule.

GENERAL PROPOSED REVISIONS

Definition of Remuneration. The Stark Law definition of "remuneration" excludes an entity's 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 believes that health care providers may interpret this exclusion as meaning that the purpose can be only one of the purposes listed above. CMS has proposed to clarify the definition of remuneration such that it will clearly state that the item must be used solely for one or more of the previously listed purposes (and for no other purposes that are not listed in the statute).

Writing Requirement. As a result of the Stark Physician Self-Referral Disclosure Protocol, CMS has become aware that providers may have misinterpreted the writing requirements of various compensation exceptions. As a result, CMS has proposed to clarify these requirements. CMS clarified in its commentary that, even in regard to lease arrangements, there is no requirement that the arrangement be documented in a single, formal contract and that a collection of documents may constitute satisfactory documentation, depending on the particular facts and circumstances of an arrangement. As such, CMS has proposed to substitute the term "arrangement" in exchange for "agreement" or "contract" in several Stark Law 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 (1) year. CMS commented that a formal contract or other document with an explicit "term" provision is generally not required to satisfy this requirement. So long as the arrangement, as a matter of fact, lasts for at least one (1) year, the requirement is satisfied. Alternatively, the parties may be able to demonstrate that 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 has proposed to amend the special rule for arrangements involving temporary noncompliance with signature requirements to allow the parties up to 90 days to obtain all required signatures, regardless of whether the late signature is advertent or inadvertent.

"Takes into Account." Many compensation exceptions to the Stark Law prohibit compensation that "takes into account" referrals. Some exceptions use other wording to mean the same thing. For example, the Physician Recruitment and Obstetrical Malpractice Insurance Subsidy Exceptions state that remuneration must not be "based on" the volume or value of referrals. The Medical Staff Incidental Benefits and Professional Courtesy Exceptions use the phrase "without regard to" in lieu of "takes into account." CMS has proposed to clarify these discrepancies by amending the Physician Recruitment, Medical Staff Incidental Benefits, Obstetrical Malpractice and Professional Courtesy exceptions² such that all of the Stark Law compensation exceptions will use the phrase "takes into account" consistently. 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.

Publicly Traded Securities. For ownership in an entity, CMS has proposed modifications and is seeking comment regarding the qualifications

for a security to be deemed "publicly traded."

HEALTH SYSTEM/PHYSICIAN RELATIONSHIPS

Timeshares. In the Proposed Rule, CMS acknowledged that timeshare leases are very common, particularly in rural areas. Due to the fact that it is often difficult for timeshare leases to comply with the Rental of Office Space Exception as a result of the exclusivity requirement, and prior guidance that the Fair Market Value Exception does not apply to leases, CMS has proposed a new Stark Law exception for timeshare arrangements where the hospital or physician organization is the "licensor." The proposed criteria for this exception are as follows:

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

CMS is seeking comments regarding whether this exception should be limited to rural and underserved areas. CMS has also proposed, and is seeking comment regarding, that per unit-of-service and percentage compensation methodologies should be prohibited for timeshare arrangements.

Holdover Provisions. The 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 has proposed to amend these holdover provisions to permit indefinite holdovers, provided that certain safeguards are met. Alternatively, CMS has proposed holdover extensions for definite periods of time (e.g., one (1) year, three (3) years, etc.). This modification would also include a revision to the Fair Market Value Compensation exception in order to permit renewals of arrangements of any length of time. Notably, CMS confirmed its position that holdover periods extending beyond six (6) months do not pose risks of abuse to patients or federal health care programs, so long as certain safeguards are in place.

Medical Staff Incidental Benefits. CMS has proposed to amend the Medical Staff Incidental Benefits Exception to replace the phrase "without regard to the volume or value of referrals" with "does not take into account the volume or value of referrals."

PHYSICIAN GROUPS

"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 has proposed that all physicians are deemed parties to the arrangement (including employees and independent contractors).

"Incident To." The Proposed Rule addresses potential revisions regarding the requirements for which physicians or other practitioners can bill for incident to services. The proposed modification would require that the physician or practitioner who bills for the incident to services

must also be the physician who directly supervises the personnel who provide the incident to services. Additionally, if the auxiliary personnel providing the incident to services have been excluded from Medicare, Medicaid or any other federal health care program, the incident to services cannot be billed. To the extent health care providers rely on Stark Law exceptions that reference "incident to" services, the revised regulations may impact those arrangements.

ACCESS TO CARE AND VALUE-BASED DEVELOPMENTS

Recruitment of Nonphysician Practitioners. In the Proposed Rule, CMS acknowledged that there have been drastic changes to the primary care workforce and the delivery of primary care services. As such, CMS has proposed a limited exception for hospitals, federally qualified health centers ("FQHCs") and rural health clinics ("RHCs") to provide remuneration to physicians in order to assist that physician with the recruitment and employment of a nonphysician practitioner. This exception would apply to remuneration provided to individual physicians, as well as physicians who stand in the shoes of their respective physician organizations. This exception would be applicable only when the nonphysician practitioner was a bona fide employee of the physician (or physician practice) receiving the remuneration from the hospital and only for practitioners who provide primary care services. CMS is also soliciting comments as to whether this exception should also apply to nonphysician practitioners who are recruited as independent contractors.

Geographic Area Served by Rural Health Centers and Federally Qualified Health Centers. In Phases II and III of the Stark Law, CMS expanded the physician recruitment exception to permit FQHCs and RHCs to make recruitment payments to physicians in the same manner as hospitals had been able to since 1995. However, in the Proposed Rule, CMS acknowledged that the definitions of geographic area serviced by a hospital depend upon the hospital's inpatient volumes. Because this metric has little applicability to FQHCs and RHCs, CMS has proposed two alternatives for adding a new definition of "geographic area" for those areas served by a FQHC or RHC. One method would involve a calculation of contiguous zip codes from which the FQHC/RHC draws at least 90 percent of its patients; the other would involve the lowest number of contiguous or noncontiguous zip codes comprising 90 percent of patients.

Retention Payments in Underserved Areas. The Retention Payments in Underserved Areas Exception permits certain payments to retain a physician in an underserved area. In Phase III, CMS modified the exception to permit hospitals, RHCs or FQHCs to retain physicians if the physician certified in writing that they had a bona fide opportunity for future employment. CMS also explained in Phase III 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. However, the regulations state that the income should be "measured over no more than a 24-month period," which CMS has stated can be interpreted differently than intended. As such, CMS has proposed to modify the regulations so that they mirror the preamble language stated above.

Physician-Owned Hospitals. CMS has proposed changes to ownership and public advertising requirements under the exception relating to physician ownership and investment in hospitals.

Impact of the Stark Law on Health Delivery Reform. In the Proposed Rule, CMS acknowledged that the Stark Law has an impact on health care delivery and payment reform. CMS has asked for comments related to perceived barriers in achieving clinical and financial integration posed by the Stark Law. Specifically, CMS is interested in comments regarding inhibitions caused by the "volume or value" and "other business generated" standards set out in the Stark Law regulations. If 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, CMS is interested in that feedback as well.

Comments on the Proposed Rule must be received by CMS no later than 5:00 PM on September 8, 2015. Comments may be submitted electronically, via mail or by hand delivery.

If you are interested in submitting a comment or would like additional information about this topic, please contact:

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Please visit the Hall Render Blog at <http://blogs.hallrender.com/> for more information on topics related to health care law.

¹ For a full text copy of the Proposed Rule, click [here](#).

² 42 C.F.R. §§411.357(e), (m), (r) and (s).