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CMS ISSUES FINAL REGULATIONS FOR PREVIOUSLY PROPOSED MODIFICATIONS TO STARK LAW

OVERVIEW

On October 30, 2015, the Centers for Medicare & Medicaid Services ("CMS") issued the final rule ("Final Rule") in follow up to the proposed rule published in July 2015 ("Proposed Rule").[1] It is anticipated that the final regulations will be published in the Federal Register on November 16, 2015. The Final Rule establishes two new exceptions to the Stark Law, clarifies certain regulatory terminology and requirements and responds to its request for comments regarding the expansion of access to necessary health care services.

This Health Law News article is intended to summarize the modifications that affect arrangements impacted by the Stark Law. Hall Render will soon be publishing additional detailed analyses of other modifications addressed by the Final Rule.

GENERAL PROPOSED REVISIONS

Definition of Remuneration. The Stark Law 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 believes that health care providers may interpret this exclusion as meaning that the purpose can be only one of the purposes listed above. CMS proposed to clarify the definition of remuneration to 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). CMS has finalized the modifications as proposed.

Writing Requirement. As a result of the recently established self-referral disclosure protocol, CMS became aware that providers may have misinterpreted the writing requirements of various compensation exceptions. As a result, CMS proposed to clarify these requirements by making the terminology in the compensation exceptions of the Stark Law more consistent and providing additional interpretative guidance. 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 upon the particular facts and circumstances of an arrangement. As such, CMS 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. In the Final Rule, CMS is not amending the term "written agreement" to "written arrangement" in the exceptions for Electronic Prescribing Items and Services and Electronic Health Records Items and Services to avoid conflict with the corresponding provisions of the Anti-Kickback Statute safe harbors; however, CMS believes that the same principles apply to these exceptions as well. In rare action by CMS, the Final Rule commentary states, "Parties considering submitting self-disclosures to the SRDP for conduct that predates the proposed rule may rely on guidance provided in this proposed rule to determine whether the party complied with the writing requirement of an applicable exception." If health care providers have questions regarding whether or not a series of documents satisfies the writing requirement, CMS has advised that the relevant inquiry is whether the contemporaneous documents permit a reasonable person to verify compliance with the applicable exception at the time that a referral is made. Note that a signature on a contemporaneous writing documenting the arrangement is still required; however, CMS provided the following list of examples of the types of documents that may constitute contemporaneous documents:

- Board meeting minutes;
- Documents authorizing payments for specified services;
- Hard copy and electronic written communications between the parties;
- Fee schedules for specified services;
- Check requests or invoices identifying items or services provided, relevant dates and/or rate of compensation;
- Time sheets documenting services performed;

- Call coverage schedules or similar documents providing dates of services to be provided;
- Accounts payable or receivable records documenting the date and rate of payment and the reason for payment; and
- Checks issued for items, services or rent.

CMS further stated that state law contract principles should not be utilized to determine what constitutes an arrangement "set out in writing" as this could result in different standards for compliance for different states.

Term Requirement. Certain Stark Law exceptions require that the arrangement have a term of at least one year. In the Proposed Rule, 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 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. In the Final Rule, CMS finalized this modification as proposed. CMS further noted that it was its intent that this modification represents CMS's existing policy. As such, any pre-existing arrangements that, in fact, had lasted at least one year are in compliance with this requirement of the Stark Law.

Temporary Noncompliance with Signature Requirements. CMS previously 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. CMS has finalized this change as proposed.

"***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 clarified these discrepancies by amending the Physician Recruitment, Medical Staff Incidental Benefits, Obstetrical Malpractice and Professional Courtesy exceptions[2] such that all of the Stark Law compensation exceptions will use the phrase "takes into account" consistently. CMS confirmed that it never intended that these exceptions be viewed as having distinguishable standards for the consideration of the volume or value of referrals. Notably, CMS specifically declined to define "takes into account"; however, CMS stated that they would consider a commenter's proposed definition of "takes into account" for the solicited comments on the need for clarification regarding permissible physician compensation.

Publicly Traded Securities. CMS finalized its proposal to except ownership or investment interests in securities listed for trading on an electronic stock market or over-the-counter quotation system, provided that quotations are published on a daily basis and trades are standardized and publicly transparent.

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 Rule contained the following criteria for the exception:

- 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 ("E/M") 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 has finalized the exception discussed in the Proposed Rule with the following modifications: 1) a timeshare arrangement must be between a physician and a hospital or physician organization; 2) equipment included under the timeshare arrangement must be in the same building as the office suite where E/M services are furnished; and 3) all locations under the timeshare arrangement, including the premises where E/M services are furnished and the premises where DHS are furnished, must be used on identical schedules. In the Final Rule, CMS also approved time-based rental fees.

Holdover Provisions. The Rental of Office Space, Rental of Equipment and Personal Service Arrangement exceptions currently permit a "holdover" arrangement for up to six months if certain criteria are met. CMS proposed to amend these holdover provisions to permit indefinite holdovers, provided that certain safeguards are met. Alternatively, CMS proposed holdover extensions for definite periods of time (e.g., one year, three years, etc.). CMS finalized the proposal for indefinite holdovers without modification. In order to prevent frequent renegotiation of short term arrangements, the holdover must continue on the same terms and conditions as the original arrangement. However, if leases are fair market value when the arrangement expires, but the rental amount falls below fair market value during the holdover period, the lease arrangement would fail to satisfy the requirements of the exception as soon as the fair market value requirement is no longer satisfied (and, subsequently, DHS referrals by the physicians to the entity would no longer be permissible). This modification also includes a revision to the Fair Market Value Compensation exception in order to permit renewals of arrangements of any length of time. In the Final Rule commentary, CMS cautioned that the failure to apply a holdover premium that is legally required by the original lease arrangement may constitute a change in the terms and conditions of the original arrangement.

Medical Staff Incidental Benefits. CMS 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." This proposal was finalized without modification.

PHYSICIAN GROUPS

"***Stand in the Shoes.***" In the Proposed Rule, CMS proposed to revise the definition of "stand in the shoes" in order to clarify that only physicians with ownership or investment interests in their physician organizations and those who voluntarily stand in the shoes of their organizations "stand in the shoes" for purposes of complying with the signature requirement. CMS has finalized this revision as proposed. To clarify, with respect to all purposes other than the signature requirement, all physicians in a physician organization (including employees and independent contractors) are considered "parties" to the compensation arrangement.

"***Incident To.***" The Proposed Rule addressed potential revisions regarding the requirements for which physicians or other practitioners can bill for incident to services. The proposed modification required 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 Final Rule's regulations may impact those arrangements.

ACCESS TO CARE AND VALUE-BASED DEVELOPMENTS

Recruitment of Non-Physician 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 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 non-physician practitioner ("NPP"). Although CMS previously declined to expand the physician recruitment exception to NPPs during the regulations promulgated in Phase III of the Stark Law, CMS has now determined that this extension of the exception is appropriate for certain employed and independent contractor physician-NPP arrangements due to changes in health care and primary care workforce shortage projections.[3] CMS made several modifications to the version of the exception it proposed in July. The

exception described in the Final Rule allows for remuneration to a physician who compensates an NPP who furnishes *substantially all* primary care services *or mental health care services* to patients of the physician's practice. As such, CMS is expanding its definition of NPP for purposes of the new exception so that it will include *clinical social workers, clinical psychologists*, physician assistants, nurse practitioners, clinical nurse specialists and certified nurse midwives. CMS declined to expand the definition of NPP to CRNAs, dieticians and physical therapists. Assistance is limited to no more than 50 percent of the aggregate compensation and benefits paid to the NPP. Additionally, hospitals, FQHCs and RHCs may only provide assistance to the same physician no more than once every three years.

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 and proposed two alternatives for adding a new definition of "geographic area" for those areas served by a FQHC or RHC. CMS chose to finalize the method that defines "geographic area served by an FQHC or RHC" as the lowest number of contiguous or noncontiguous zip codes comprising 90 percent of patients as determined on an encounter basis.

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 prior regulations stated that the income should be "measured over no more than a 24-month period," which CMS noted in the Proposed Rule can be interpreted differently than intended. As such, CMS finalized the regulatory modifications as proposed so that they mirror the preamble language stated above.

Solicitation of Comments. CMS reiterated its intent to move Medicare payments away from providers and suppliers that do not incorporate the value of the care provided. The Secretary has recently set several goals related to the conversion of fee-for-service payments to quality and value-based payments. CMS acknowledges that historically the Stark Law has separated entities furnishing DHS from the physicians who refer Medicare patients to them. However, evolving health care delivery and payment models require closer integration of health care providers to improve population health and quality of care while reducing costs. CMS received many comments on this issue that were not addressed in the Final Rule. CMS is going to utilize these comments in a report prepared for Congress to determine whether additional rulemaking is necessary.

If you would like additional information about this topic, please contact:

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[1] For a summary of the Proposed Rule, click here. [2] 42 C.F.R. §§411.357(e), (m), (r) and (s). [3] The citation of this exception will be 42 C.F.R. § 411.357(x).