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Stark Liberalizations?!: Significance to Physicians

This newsletter is not legal advice, It is informational only. Any reader should consult an attorney for legal advice.

In 2015, with the Medicare Physician Fee Schedule, CMS published the first significant regulatory changes to the Stark program in many years. They included issues such as permitting recruitment support for non-physician practitioners (NPPs), reducing burden on physicians by liberalizing prior requirements, clarifying definitions, addressing publicly traded securities, creating a new exception for time sharing of space, modifying their requirements regarding temporary non-compliance with signature requirements as well as issues pertaining to physician-owned hospitals and the very technical 'stand in the shoes' principle. We are addressing these now because unlike prior Stark changes, they did not require immediate changes in behavior, but permit more relaxed considerations. We address here only those changes most significant to physician practices as a practical matter.

Burden Reduction

The new changes addressed two specific reductions in administrative burden in the implementation of Stark.

1. <u>"Written Agreement"</u>

Somewhat surprisingly given the general rigidity of the regulations, the regulators have attempted to reduce burden and improve clarity regarding the writing, term and holdover provisions that apply in certain exceptions. There had been the belief that for a number of the compensation exceptions, the arrangement had to be stated in "a written agreement" signed by the parties. Now, to satisfy the writing requirement, the arrangement must be sufficiently documented to permit the government to verify compliance with the applicable exception, but there is no requirement that the arrangement be constituted in a single formal contract.

> *"Depending on the facts and circumstances of the arrangement and the documentation, a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing*

requirement of the easing exceptions and other exceptions that require that an arrangement be set out in writing."[1]

Though this clarification is a benefit to people who have not entered into agreements, we still think that to have an agreement that documents the intentions of the parties and sets out bases for compensation and termination, is the safer course. We do see this change as useful in defending transactions as compliant.

With regard to signatures, the parties do not need to sign a single formal document to comply with the signature requirement of an applicable exception, nor do they expect every document in a collection of documents to bear the signature of one or both parties. To satisfy the signature requirement, a signature is required on a contemporaneous writing which documents the arrangement.

Amazingly, they offer examples of how a collection of documents might substantiate an arrangement including board meeting minutes or other documents authorizing payments for specified services; written communication between the parties including hard copy and electronic communication; 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. Among other things, the documents must clearly relate to one another and evidence the same arrangement between the parties.

In a similar easing of restrictions, with regard to the exceptions for the rental of office space, the rental of equipment and personal services arrangements, the regulations have required that the arrangement must have a term of at least one year. Based on issues that have been submitted pursuant to the Self-Referral Disclosure Protocol, they have taken the position that the term of at least one year need not be stated per se. An arrangement that lasts, as a matter of fact, for at least one year would satisfy the requirement that the arrangement must exist for at least one year. The parties must have contemporaneous writings establishing that the arrangement lasted for at least one year or be able to demonstrate that the arrangement was terminated during the first year and that the parties did not enter into a new arrangement for the same space, equipment or services during the first year. This represents a refreshing change which acknowledges the practicalities of physicians' business lives.

2. <u>Holdovers</u>

With regard to holdover arrangements permitted for lease exceptions, originally the regulations permitted a holdover for up to six months if the arrangement for at least

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[1] 80 Fed. Reg. 71315 (November 16, 2015).

one year had expired, as long as the requirements of the exception remained satisfied and their arrangement continued on the same terms and conditions. In the 2015 publication, they have removed the requirement of six months, permitting an indefinite holdover arrangement as long as it is on the same terms and conditions as the original agreement. If, for example, during a term while a lease was expired, the rental amount continued from previously no longer reflects fair market value, the holdover permission is not satisfied. An expired writing by itself could not constitute compliance with the holdover provision. There would have to be additional supporting documentation documenting a course of conduct that would substantiate that the arrangement continued on the same terms as previously. It is also legitimate to charge a holdover premium, but a holdover premium legally required by the original agreement but not charged for during the period of expiration may constitute a change in the terms of the original agreement which would preclude the application of the exception.

Timeshare Arrangements

In a surprising approach to expanding access and liberalizing a range of exceptions which had required office space to be used exclusively by the lessee, they have created a new exception for timeshare arrangements. Recognizing that it is relatively common for a hospital or local physician practice to make available its offices, including personnel and equipment to physicians who may use the space during the time that the practice is continuing to function, they are allowing such arrangements, permitting the use of office space, equipment, personnel, items, supplies, or services. The timeshare arrangement exception may be used where the arrangement is set out in writing, signed by the parties and specifies the premises, equipment, personnel, items, supplies and services covered. It is not available for everyone: the arrangement must exist between a physician or the physician organization in whose shoes the physician stands on one hand and a hospital or a physician organization on the other. In addition, the arrangement must be predominantly for the provision of evaluation and management (E/M) services to patients and on the same schedule as the E/M services. The equipment covered must be located in the same building where the E/M services are furnished and may not be used to furnish designated health services other than those incidental to the E/M services furnished at the time of the patient's E/M visit. The regulations specifically exclude advanced imaging equipment, radiation therapy equipment or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).

The compensation must 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 or using a formula based (1) on a percentage of the revenue raised, earned, billed, collected or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies or services covered by the arrangement; or (2) a per unit of service fees that are not time based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises. The regulators have specifically said that they are not prescribing how parties determine compliance with the

timeshare arrangement. They may determine the fee for the arrangement and may base it on reasonable, objective and verifiable means, which, depending on the circumstances, may include assessing the volume of patients seen, the number of patient encounters, the types of CPT codes billed, or the amount time spent using the timeshare premises, equipment, personnel, items, supplies and services.

Definitions

The regulators have clarified some definitions to ease the restrictions in the application of the law.

1. "Remuneration"

Noteworthy among the changes is that 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 do not constitute remuneration under the definitions. Furthermore, the provision of such items or devices is not considered to be remuneration itself. provided that the device or supply is used for one or more of the six purposes listed in the statute and for no other purpose.

They also clarified that in a split bill arrangement where a physician makes use of a DHS entity's resources (for example, examination rooms, nursing personnel, and supplies) to treat the DHS entity's patients, if the DHS entity bills for its component of the services while the physician bills his or her own component of the services, this does not constitute remuneration between the parties. In contrast, if a physician or DHS entity bills a non-Medicare payor (e.g. a commercial payor or self-paid patient) globally for both the physician's services and the DHS entity's resources and services, a benefit is conferred and the global arrangement does involve remuneration between parties that implicates the physician self-referral law.

2. Locum Tenens

Ironically, in the regulation addressing locum tenens physicians, the term "stand in the shoes" was originally used to describe the role that physician plays for the physician for whom he is substituting. In the 2015 publication, "stand in the shoes" has been removed from the definition, although the principle remains in place for the highly technical issue of physicians "standing in the shoes" of their corporations when analyzing relationships.

NPP Recruitment Assistance

The statutory language itself has always provided for some support to be made available by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital. The regulatory exception extended the protection to payments that were made to a group that was recruiting a physician. Originally, the regulators

declined to extend protection to recruitment for NPPs; but with NPPs the fastest growing segment of the primary care workforce combined with evolving care delivery models, a new exception was created effective January 1, 2016. The exception is not available to all takers.

The exception permits remuneration from a hospital, Federally Qualified Health Center (FQHC) or Rural Health Center (RHC) to a physician or group to assist the physician in employing an NPP in the geographic area served by the hospital, FQHC, or RHC providing remuneration. The goal of the regulation is to promote the expansion of access to primary care services – which the regulators consider to include general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology patient care services. However, the NPPs included in the ambit of the exception are only physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified nurse midwives (CNMs). The exception is for remuneration to assist the physician with compensating an NPP to provide primary care services or mental health care services to patients of the physician's practices. Because of the need for mental health professionals as well, NPPs, only for purposes of this exception, also include clinical social workers and clinical psychologists. While in the separate fee schedule, CRNAs were added to the list of distant site practitioners for telehealth services, they are not included in the definition of an NPP for purposes of the physician self-referral exception.

There is not a requirement that the NPP be employed on a W-2. Whatever mechanism the physician uses to employ, contract with, or otherwise engage an NPP under a compensation arrangement to furnish primary care services or mental health care services to patients of the physician's practice is permitted. Interestingly, in the commentary, the regulators made clear that the exception is available to any physician who compensates an NPP to furnish primary care services or mental health services to patients of the physician's practice, even if that specialty is not itself primary care. However, any assistance to the physician must be to compensate an NPP to furnish primary care or mental health care services.

As to the issue of whether a minimum amount of primary care services would have to be provided to receive the financial support, the standard the regulators settled on was "substantially all" which, consistent with the other physician relevant regulations related to the definition of a group practice, is 75% of the NPP's services. The patient care services that form the basis to measure the NPP's performance are either the total time the NPP spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries); or any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, informally applied over time, verifiable and documented.

The total amount of financial support which may be made available is an amount that does not exceed 50% of the actual aggregate compensation, signing bonus and benefits paid to the NPP who joined the practice. This is quite different from the physician recruitment protection which permits the physicians' total salary and

incremental costs of employment to be subsidized. Here, benefits are intended to include only health insurance, paid leave, and other routine non-cash benefits offered to similarly situated employees of the physician's practice. Nothing would preclude the inclusion of relocation costs as long as they are calculated in the aggregate compensation from the physician to the NPP; and they must be consistent with fair market value.

Like the physician recruitment exception, there is a three year limitation on the frequency of a hospital's, FQHC's or RHC's use of the exception for a particular physician. There is also a total two year limit on the assistance made available to employ or contract with the NPP. The exception is not available to compensate a physician who engages an NPP who already furnishes patient care services in the geographic area served by the entity remunerating the physician. Commenters requested that, like the physician recruitment assistance exception, for an NPP coming out of training an exception would be made even if they had been in training in the same area. CMS declined to make that available.

In determining the geographic area that is relevant to the entity remunerating the physician, similar to the physician recruitment exception, the geographic area is determined by the lowest number of contiguous or non-contiguous zip codes from which the FQHC or RHC draws at least 90% of its patients determined on an encounter basis.

The new NPP exception brought the regulators to the point of reevaluating retention payments to be made to physicians under highly limited circumstances in underserved areas. The amount of the assistance is now stated to be an amount equal to 25% of the physician's current annual income (averaged over the previous 24 months) using a reasonable and consistent methodology that is calculated uniformly or the reasonable cost that the hospital would have to expend to recruit a new physician to the area served by the hospital to join the medical staff of the hospital to replace the retained physician.

Temporary Non-Compliance

Along the lines of the burden-lifting provisions noted above, they have added a new exception pertaining to temporary non-compliance with signature requirements. Before the 2015 publication, there was a special rule for arrangements involving temporary non-compliance with signature requirements to permit an entity to submit a claim or bill and receive payment for DHS if an arrangement temporarily did not satisfy the applicable exception's signature requirement but otherwise fully complied. Under that rule, if the failure to comply with the signature requirement was inadvertent, the parties had to obtain the required signature within 90 days. Determining the intent of the parties when the signature requirement was not met would be difficult at best.

In the 2015 rule change, the arrangement has to satisfy all of the requirements of an applicable exception, including that it be set out in writing. In addition, an entity may make use of the regulation only once every three years for the same referring physician. They have extended the time frame within which to obtain signatures to 90 days,

regardless of whether the failure to obtain the signatures was inadvertent or not inadvertent. If the arrangement is with a physician group, the three year preclusion extends to every physician who is in the group. If, however, the arrangement is with an individual member of the group, then it could be used with another individual member of the group within a three year period.

Conclusion

The Stark statute is the single worst piece of legislation we deal with- -overly complicated, highly technical, and not very helpful. The regulators have struggled to make sense of it over the years. Although there is little current prospect for its repeal , at least the new regulations reflect some understanding of how burdensome the law is. We can be grateful for small favors.