CLIENT ALERTS & INSIGHTS

Stark Law – Is Relief in Sight?

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CMS Announces Proposed Stark Law Revisions

On July 15, 2015, the Centers for Medicare and Medicaid Services ("**CMS**") published proposed revisions to the regulations implementing the physician self-referral law, or Stark Law. If enacted, these revisions could allow healthcare providers greater flexibility in their physician relationships and help them avoid high financial penalties for purely technical violations.

Stark Law Background

The Stark Law governs relationships between physicians and the providers to which they refer certain designated health services ("**DHS**"). DHS includes many commonly ordered health care services, such as durable medical equipment, home health care, physical therapy, laboratory and imaging.

The Stark Law was enacted in response to concerns about overutilization of DHS within the Medicare program. Its restrictions were intended to ensure that all financial relationships between DHS providers and physicians were for legitimate services, rather than disguised incentives to encourage physicians to order DHS that was not medically necessary or to choose a particular provider of DHS for reasons other than the best interests of the patient.

In order to receive Medicare reimbursement for DHS, all financial relationships between an entity furnishing or providing DHS ("DHS Entity") and the referring physician must satisfy a statutory or regulatory exception to the Stark Law. The Stark Law contains exceptions for a variety of financial relationships, including space and equipment leases, employment and personal service arrangements, certain ownership interests in physician practices and other entities, and many other common compensation and ownership relationships.

However, these regulatory exceptions are complex and contain many technical requirements. The Stark Law is a strict liability statute, meaning that if a financial relationship fails to comply with any one of an exception's requirements, the Stark Law is violated and the DHS Entity cannot seek Medicare reimbursement for those services. Any Medicare reimbursement received from a referral in violation of the Stark Law must be repaid, and the DHS Entity may be subject to additional penalties.

Overview of the Regulations

Over the past few years, many DHS Entities have entered into significant settlements to resolve what are often perceived as purely technical violations of the Stark Law. These DHS Entities have paid millions of dollars in penalties in connection with expired leases, forgotten signatures or other minor Stark Law violations that most agree pose a minimal risk to program integrity.

Reflecting awareness of this fact, CMS is proposing a number of clarifications and revisions to the Stark Law that will allow greater flexibility in satisfying a Stark Law exception, while still requiring the parties to have legitimate arrangements for fair market value compensation. In addition, CMS has standardized language throughout the Stark Law exceptions.

Finally, CMS has proposed two new exceptions designed to reflect the changing delivery of health care in America, with the rising use of nonphysician practitioners in primary care and growing demand for flexible working arrangements between hospitals and physicians.

Highlights of the proposed revisions, and their potential impact on physicians and DHS Entities, are described below.

Proposed Revisions

· ***Writing Requirements*.**

Many of the Stark Law exceptions currently require the relationship between the parties to be "set out in writing" or be pursuant to a "written agreement." CMS proposes to standardize the language among all the exceptions, requiring an "arrangement" that must be "set out in writing." CMS has further clarified that the "arrangement" does not have to be one formal, written contract. For the first time, CMS has expressly stated that the Stark Law exceptions can potentially be satisfied by multiple documents or other written evidence establishing the course of conduct between the parties.

There has long been confusion in the provider community regarding what constitutes a sufficient writing for purposes of satisfying these exceptions. CMS' commentary suggests that any number of things, such as a chain of emails between a physician and a DHS Entity establishing the terms of the relationship, can now clearly be used to satisfy an exception. DHS Entities and physician must still be able to demonstrate that these arrangements, however established, satisfy the other requirements of the applicable Stark Law exception, such as those regarding term and compensation.

A comprehensive written contract remains the best practice for any number of reasons, including clearly establishing the rights and responsibilities of the parties and providing for indemnification, insurance requirements and other contractual liability matters beyond the scope of the Stark Law. However, when such a contract has not or cannot be entered into for any reason, DHS Entities and physicians will now have greater flexibility in establishing that the Stark Law requirements have nonetheless been satisfied.

· ***Holdovers*.**

One of the most common technical violations of the Stark Law occurs when parties continue to operate under leases or personal service arrangements that have technically expired. Under current regulations, parties may only continue to operate under such an arrangement for 6 months. If they continue beyond this period, even if they are otherwise operating in full compliance with the compensation provisions and other terms of the arrangement, the Stark Law has been violated. The DHS Entity cannot seek Medicare reimbursement for referrals of DHS made by a physician involved in such arrangement. Because the Stark Law is a strict liability statute, it does not matter if the

parties mistakenly believed that a contract automatically renewed or otherwise unintentionally extended their relationship beyond the agreement's terms.

Such accidental violations of the Stark Law have been the subject of provider self-disclosures leading to millions of dollars in penalties. Under the proposed regulations, however, parties may now continue to provide services under leases and personal service agreements that have technically expired for an indefinite period without violating the Stark Law.

This will provide welcome relief for many providers who discover a contract that expired several years ago and was never formally renewed. However, it is important to note that the parties must otherwise comply with the terms of the expired contract. If the parties have adjusted compensation rates or other contract terms beyond that provided for in the written contract, the arrangement will not be in compliance with the Stark Law, and the referral prohibition will still apply.

· ***Signature Requirements.***

Many Stark Law exceptions require the arrangement between the parties to be signed. Previously, in most circumstances, signatures had to be obtained within 30 days after the services started for the arrangement to be considered compliant with the Stark Law.

The proposed regulations will allow the signatures to be obtained up to 90 days after services begin. As with the other proposed changes, this will allow for greater flexibility in satisfying the technical requirements of the Stark Law exceptions. The parties to an arrangement implicating the Stark Law still need to carefully track signatures and make sure they do not miss the extended deadline.

· ***Term Requirements.***

Many of the Stark Law exceptions require the parties to have an agreement for at least one year. CMS is clarifying that the contract or agreement between the parties does not have to have an explicit one-year term, so long as the relationship does in fact last one year. If the relationship is terminated before one year has passed, consistent with prior guidance, the parties cannot enter into the same or similar arrangement for the remainder of the year.

New Exceptions

· ***Recruitment of Nonphysician Practitioners (NPPs).***

CMS is proposing a new exception that would allow hospitals and other providers to provide recruitment support for nurse practitioners and other NPPs. Previously, this support had only been allowed for physicians.

This is an important new exception, reflecting the growing use of NPPs in the delivery of primary healthcare services. Only hospitals, federally qualified health clinics and rural health clinics may take advantage of this new exception. The NPP must be a bona fide employee of the physician or physician organization receiving the recruitment support, and the practitioners must provide primary care services.

The arrangement must also meet the following requirements:

(1) It must be set forth in a writing signed by all parties.

(2) The arrangement cannot be conditioned on the physician's or the NPP's referrals to the party providing the recruitment support. The recruitment compensation also cannot take into account the volume or value of such referrals.

(3) The recruitment support cannot exceed the lower of: (a) 50% of the NPP's salary, signing bonus and benefits during the first 2 years of employment; *or* (b)the difference between the revenues generated by the NPP and the NPP's salary, signing bonus and benefits during the first 2 years of the NPP's employment.

(4) The salary, signing bonus and benefits paid to the NPP cannot exceed the fair market value of the patient care services furnished by the NPP.

(5) The NPP cannot have practiced within the hospital's geographic service area or been employed or contracted by the physician in the past 3 years.

(6) The arrangement cannot violate the Anti-Kickback Statute or other federal or state laws governing billing and claims submission.

· ***Timeshare Arrangements.***

CMS is proposing a new exception that would allow hospitals and physician organizations to enter into timeshare arrangements with physicians for the use of office space, equipment, personnel, supplies and other services. CMS states that it recognizes that such arrangements are an important aspect of healthcare delivery, especially in rural areas. However, structuring them to meet the existing Stark Law exception for space leases is often difficult, because the exception is designed for full-time, exclusive use of the leased space.

Under the proposed regulation, only a hospital or physician organization may be the "licensor" of the space. The license must meet the following requirements:

(1) The arrangement must be in a signed writing.

(2) The arrangement must specify the premises, equipment, personnel and other supplies or services covered. Certain equipment cannot be licensed, including many advanced imaging, laboratory or other equipment used to provide complex services.

(3) The premises must be used primarily for the evaluation and management of the physician's patients.

(4) The arrangement cannot be conditioned on the physician's referrals to the licensor, and the compensation cannot take into the account the volume or value of such referrals.

(5) The compensation paid by the physician must be set in advance, consistent with fair market value and commercially reasonable.

(6) The arrangement cannot violate the Anti-Kickback Statute or other state and federal laws related to billing practice and reimbursement claims.

The new license exception has the potential to give hospitals and physicians greater flexibility in crafting temporary arrangements. However, it will be important to make sure these new licenses are

carefully structured to meet the exception's requirements. Valuations and other third-party confirmations of the compensation paid by the physician licensee should be carefully considered.

If these proposed regulations are enacted, parties involved in arrangements implicating the Stark Law may see greater flexibility in how they can demonstrate compliance. However, it will still be important to carefully document physician relationships and track compensation to ensure that Stark Law violations do not occur.

Providers who may be impacted by these proposed changes are encouraged to submit comments to CMS. In addition to comments on the proposed regulations, CMS has requested stakeholders to provide feedback on how the Stark Law's restrictions have affected their ability to participate in alternative delivery models encouraged by other healthcare reforms, including the Affordable Care Act. Comments may be submitted electronically here and should be received by September 8, 2015.

If you have questions about the impact of these proposed regulation or are interested in submitting comments, please contact any member of the Benesch Health Law group.
