Stark Clarifications

Recently there have been new releases and clarifications to the Stark regulations. There are so many aspects to these regulations there is no possible way we can evaluate each in this article so we have decided to identify the most pressing issues in our opinion and share their impact with you.

As responsible healthcare professionals we want to provide you with background on each of the issues and then provide our commentary to help you understand how these issues impact your practice. Where guidance is possible we provide you our opinions on how you should approach each of these issues but, please realize we are not and cannot provide legal advise because we are not attorneys. Please be responsible on your end as a healthcare professional and consult your own legal counsel for advice and/or guidance on these highly complex issues. Nothing in these articles should be taken as legal advice.

Revisions to "Stand in the Shoes"

This rule looks at both direct and indirect compensation for physician. According to Stark III there was inclusion for a "stand in the shoes" provision under which referring physicians are treated as "standing in the shoes" of their physician organizations for purposes of applying the rules for direct and indirect compensation arrangements. The rule goes on to clarify and define what a "physician organization" is (including a Professional Corporation of which the physician is the owner), a physician practice, or a group practice (as defined under §411.352). This raised a lot of concerns with academic medical centers and from and integrated "tax-exempt" delivery health systems. The concerns raised by these groups, was related to certain support payments. As CMS normally does when there are a large volume of comments or complaints, they delayed the effective date of the "stand in the shoes" provisions for arrangements involving academic medical centers' faculty practice plans and compensation arrangements between affiliated Designated Health Services entities and physicians in integrated delivery health systems (more information is available under 501(c)(3)).

There have now been additional clarifications in the Stark IV language for the "stand in the shoes" provisions. CMS has provided a clarification that tells when a physician must and when a physician may, "stand in the shoes" of his or her physician organization. What this means is, any physician(s) who have ownership or investment interest in a physician organization must be treated as standing in the shoes of that physician organization.

In contrast, a physician with a with only title ownership interest is not required to stand in the shoes of their physician organizations, although they are permitted to do so. CMS has defined what is referred to as a "titular" ownership or investment interest in the following manner; "Interest that does not include the ability or right to receive financial benefits or ownership or investment, including distribution or profits, dividends, proceeds of sale or similar returns on investment."

The "stand in the shoes" requirements will not apply to an arrangement that satisfies the Academic Medical Center exception, which can be found in §411.355(e). Although the stand in the shoes revisions went into effect on October 1, 2008, CMS has indicated that these provisions will not apply to an arrangement which met the indirect compensation exception's requirements as of September 5, 2007, or which meets an exception that can be found in §411.357(other than the indirect compensation exception) as of the date the Stark IV rules are published in the Federal Register.

Changes to Definition of Entity/Under Arrangements.

There was a proposal to change the definition of what is an "entity." This proposal was part of the 2008 Medicare Physician Fee Schedule. The proposed definition of "entity" was so that a person or entity would be considered to be furnishing Designated Health Services if it "performed" the Designated Health Services, or presented or caused a claim to be presented for Designated

Health Services. This is in line with what we explain to clients all the time. The government no longer has to demonstrate intent on the part of the entity to commit fraud they only have to show that a claim was submitted and monies were paid to the entity inappropriately. This is significant to the healthcare industry due to the impact on "under arrangements" ventures. This is where an entity such as a physician organization or joint venture, provides services to a hospital "under arrangements," and the hospital bills for the services as inpatient or outpatient services. This is going to mean many providers that are currently working under these types of arrangements are going to have to have their arrangements restructured with the hospital with whom, they have their current agreement. There is a delay on the implementation of this proposal under Stark IV until October 1, 2009. This should give providers working under these types of arrangements time to work with their legal counsel to get things restructured to comply with the new language.

It should also be noted that CMS noted in the comments that it did not consider an entity that performed Designated Health Services to be: (i) leases or sells space or equipment used for the performance of the service, or (ii) furnishes supplies that are not separately billable but are used in the performance of the service, or (iii) provides management, billing services or personnel to the entity performing the service to be "performing Designated Health Services" for purposes of the regulation.

Alternate Method for Compliance

Compliance is such a major part of everything we do in a medical practice and with the CMS proposal in the 2008 Physician Fee Schedule for an alternate method of satisfying requirements for certain exceptions to the Stark regulations. This proposal is intended to assist providers when the failure to meet the requirements was based on some type of procedural issue (a missing signature). There were eight (8) criteria outlined in the original proposal a provider would need to demonstrate in order to avail him/herself of the protection of the alternate method of compliance. Of these eight (8) criteria in our opinion the most significant was a requirement that the provider be required to self-disclose the noncompliance to CMS.

As we have become accustomed to with CMS Stark IV substantially revises the original proposal. The new proposal calls for payment to be if a financial relationship complied with one of the applicable compensation exceptions, with the exception of a signature requirement, if (i) the signature is obtained within 90 days if the failure to obtain the signature was inadvertent; (ii) the signature is obtained within 30 days if the failure was not inadvertent. Here is the kicker to this proposal; the exception may only be used by the entity only once every 3 years with respect to the same referring physician. This exception became effective October 1, 2008.

Burden of Proof

This section serves as a clarification by CMS with regard to any appeal of a denial of payment for Designated Health Services that was made on the basis of a prohibited referral, the burden of proof is on the entity submitting the claim to establish it was not furnished pursuant to a prohibited referral. What this means is that you will have to perform some research to identify when the rule became effective, by which a service was added to the list of Designated Health Services.

Period of Disallowance

As listed in Stark IV, CMS provides that the period of disallowance begins at the time the financial relationship fails to meet the

requirements of an exception and ends not later than:

If the noncompliance is not related to compensation, the date the relationship satisfies all requirements of an applicable exception;

If the noncompliance relates to the payment of excess compensation, the date the excess compensation is repaid in full and the financial relationship satisfies all of the requirements of an applicable exception;

If the noncompliance relates to the payment of less than sufficient compensation, the date the additional compensation is paid and the financial relationship satisfies all of the requirements of an applicable exception.

There is no requirement of self-disclosure by the entity for them to be able to use the disallowance period regulation. These regulations became effective October 1, 2008.

There are, as stated at the beginning of this article several other aspects to the Stark regulations and we strongly encourage you to look to some of these areas listed below and familiarize yourself with them to ensure your compliance with the regulations.

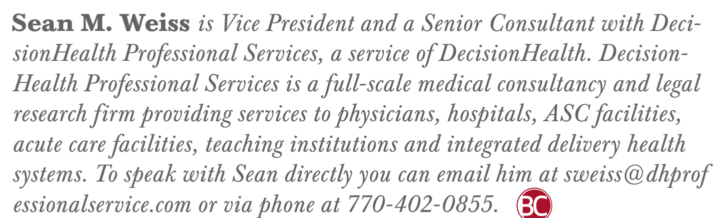
- Obstetrical Malpractice Insurance Subsidies
- Clarification Concerning Phase III Amendment vs. Termination Rules
- Limitations on Percentage-Based, Per-Click and Per-Use Arrangements.
- Exception for Ownership/Investment Interests in a Retirement Plan

Bringing it All Together

As you were hopefully able to gather from the different sections discussed above what appears to be most potentially helpful of the changes in the newest Stark Regulations are the "stand in the shoes" provisions. This is due to the fact the rule permits continued use of the indirect compensation terms of the Stark regulations whenever a financial relationship is with employed physicians who are not shareholders or owners of a physician group.

Keep in mind the period of disallowance rules, and the new "under arrangements" rules are further clearly evidence CMS is bent on continuing to tighten the rules that surround physician relationships with hospitals as well as with other entities that receive patient referrals from physicians.

Source- 42 CFR Parts 411, 412, 413, 422, and 489 Medicare Program; Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; and Collection of Information Regarding Financial Relationships Between Hospitals; Final Rule



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