

LEGAL ALERT

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THE IMPLICATIONS OF STARK III

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On September 5, 2007, the Centers for Medicare and Medicare Services (“CMS”) published Phase III of its regulations regarding Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships, likely to be known as “Stark III.” The rule comes in response to public comments regarding Phase II of the Stark regulation published in March 2004, and is intended to “finalize” the Stark regulations. Despite the characterization of these regulations as “final,” CMS has already issued further proposed revisions to the Stark regulations as part of its Medicare Physician Fee Schedule proposed rule, issued in July 2007 (the “Proposed Changes”).

Read together, the Final Rule and the Proposed Changes reveal some meaningful changes to the Stark regulations and the types of arrangements that will be permissible going forward. **Certain of these changes could ultimately require that many financial transactions currently in place between physicians and entities that provide designated health services (a “DHS Entity”) be undone and/or significantly modified.**

Unfortunately, until CMS publishes the Final Rule for the Medicare Physician Fee Schedule, it will be impossible for health care providers – potentially implicated by these changes – to know for certain the scope of work that will be necessary to bring many of their existing or anticipated financial relationships into regulatory compliance.

With that background, some of the more

significant changes that we know will be effective on December 4, 2007 include the following:

- The safe harbor definition for “fair market value” has been eliminated and health care providers are now left to their individual judgment as to how to evaluate and determine fair market value and to determine the appropriate level of supporting data that needs to be maintained to justify fair market value where it is required by a Stark exception.
- In order to address CMS’ concerns that health care providers are constructing financial arrangements between physicians and DHS Entities through the use of the indirect compensation arrangement exception, CMS has expanded the notion of when a physician “stands in the shoes” of his group practice. Essentially, what CMS has done has narrowed the application of the indirect compensation arrangement safe harbor by requiring that referring physicians stand in the shoes of their group practice with respect to any financial relationships that may exist between that group practice and a DHS Entity. Any financial relationships in place between a group practice and a DHS Entity must now be analyzed as if a direct financial relationship exists between the referring physicians who are members of the group and the DHS Entity.
- Because CMS anticipates that as a result of this change in the regulation, certain

existing financial arrangements may have to be modified to fit within an appropriately applied Stark exception, CMS has provided that arrangements entered into prior to the publication date of Stark III (September 5, 2007) and that satisfy the requirements of the indirect compensation arrangement exception as of that date, do not need to be amended or renegotiated during their original term or any current renewal term. **However, at the end of the financial arrangement's existing term, whether it is original or renewal, the entire arrangement must be restructured so as to fit within the appropriate direct compensation arrangement exception under Stark.**

- Through the comment process, CMS has clarified its expectation that a contract reflecting a financial arrangement between a physician and a DHS Entity may be amended without violating any applicable “set in advance” requirements so long as the amendment is made for a bona fide reason and so long as the bona fide reason is not for the purpose of taking into account the volume or value of referrals or other business generated between parties.
- Despite its clarification regarding the ability to amend certain financial arrangements without violating the “set in advance” concept, CMS also clarified that with respect to lease agreements, it is not permissible to amend a lease agreement for the purpose of changing the rental rates as set forth in the original agreement, during the term of the original lease. Any amendments to a lease agreement for the express purpose of altering rental rates has to be completed through the execution of an entirely new lease agreement, consistent with other Stark limitations. However, CMS also clarified that the hold-over lease provisions do not prohibit a landlord from charging a hold-over lease

rate that is higher than the lease rate provided during the original lease term, so long as the higher hold-over lease rate is set at the time of the execution of the original lease.

- In several different locations within Stark III, CMS answers questions and comments with regard to the “physician in a group practice” concept and repeatedly clarifies that referrals made between and among physicians in a group practice are permissible under different circumstances depending upon whether the physicians to whom patients are referred are, in fact, “members of a group” or merely independent contractors with the group. **Group practices who rely on the in-office ancillary services exception to justify certain referral relationships within and among group members should take great care to ensure that existing physician referrals are not problematic as a result of these clarifications made within Stark III.**
- CMS expresses a belief in Stark III that most “shared facility arrangements” or “per-use” fee arrangements that are currently in existence do not meet the supervision requirements of the in-office ancillary services exception under Stark or the Anti-Kickback statute. **Physician groups involved in such arrangements should, again, take great care to have those financial arrangements analyzed to ensure that, in fact, those arrangements do meet the expectations and express interpretations of CMS as reflected in Stark III.**
- CMS also makes several clarifications and changes with regard to the physician recruitment exception and has provided DHS Entities with the freedom to negotiate more generous income guarantee arrangements than might otherwise be

allowed if the purpose of recruiting a physician to the community is to replace a deceased, retiring, or relocating physician. In addition, CMS has agreed that group practices should be allowed to put in place certain types of practice restrictions on physicians who are recruited into a group practice, although direct non-compete covenants and restrictions are still prohibited. CMS made other significant clarifications with regard to the application of the physician recruitment exception and **DHS Entities that have entered into physician recruitment arrangements since 2004 will find it worthwhile to have those arrangements reviewed to ensure that as a result of CMS' "clarifications," none of these existing arrangements have fallen out of compliance with Stark.**

- CMS expanded the application of the fair market value exception to cover not only payments to physicians, but also payments from physicians to DHS Entities. However, CMS also clarified that the fair market value exception is not available for financial arrangements that involve the rental of office space.
- With regard to the non-monetary compensation exception, CMS has clarified that its expectation is that the annual dollar limit of non-monetary compensation that a DHS Entity may provide to a physician is an "entity specific" dollar limit. This means that for health systems that have multiple DHS Entities, each entity has its own individual

dollar limit as it relates to each physician rather than a single limit for the entire system. However, **CMS also clarifies that its expectation is that each DHS Entity will have a system in place for tracking all non-monetary benefits irrespective of how difficult it may be for hospitals and health systems to track and identify those benefits.**

While the above is only a brief summary of the types of changes being made in Stark III, health care providers need to be aware that the Proposed Changes could have even greater implications for existing financial relationships, particularly as they relate to purchased diagnostic services, per click financial arrangements, and certain "under arrangement" arrangements between physicians and DHS Entities. As a result, health care providers who are in financial arrangements potentially implicated by the Stark regulations should expect that over the course of the next 90 days, a significant amount of their compliance resources need to be devoted to a full and complete analysis of all of the Stark changes and their implications.

Interested readers can find a "red lined" copy of the Stark regulations which reflect the changes to these regulations at:

http://www.cms.hhs.gov/PhysicianSelfReferral/Downloads/Unofficial_Redlined_411_350.pdf.

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