

# Are You Ready for the Final Stark II Regulations?

Oct 01 2001

Practice Area: Health Law

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Like it or not, the final Stark II regulations will become effective - at least in part - in 2002. Although overall the new regulations are confusing, elaborately complex, and often counter to common sense, there is no doubt that they are here, they are the law, and enforcement is beginning.

## **FOCUS ON HOSPITALS**

Some of the rules established in the January 4, 2001 Stark II, Phase I regulations are helpful. The 11 categories of Designated Health Services (DHS) are now more clearly defined. A number of DHS categories, such as radiology, are now delineated by a list of CPT codes published by CMS. If it is on the list, it is a DHS, if not, it is not.

Most complex in Stark II are the changes related to the interpretation of Stark in connection with hospital compensation to physicians for items or services. In an attempt to correct prior inconsistencies and contradictions, CMS has created four "special rules on compensation" to establish how CMS will interpret common Stark requirements.

Under the new special rules, independent contractors will no longer be able to be compensated based on a percentage of collections or revenue, and the exceptions that preclude payments based on "other business generated between the parties" will preclude payments based even on nongovernment paid services.

## **FOCUS ON PHYSICIANS**

Physician group practices face a brave new world of what it means to be a "group practice" under Stark. In order for a multi-physician practice to continue to allow referrals to the practice for ancillary services, the group must qualify as a "group practice." While many requirements for being a group practice have been clarified and made more easy to comply with, a group must be assured that it meets all of the nine requirements, or referrals to the practice by its physicians may be prohibited.

For both hospitals and physicians, the new regulations make one thing clear: hospitals cannot directly operate a group practice as a division of the hospital. To meet the "single legal entity" requirement, the group cannot be part of another organization, and CMS has made it clear that this applies to hospitals.

## **NEW EXCEPTIONS**

The Stark II, Phase I regulations create five new exceptions for various compensation arrangements for physicians.

- Non-monetary compensation under \$300 per year. In addition to other requirements, this exception prohibits any cash or cash equivalent payments, and CMS seems to be equating gift certificates with cash equivalents.
- Incidental benefits to medical staff. This exception has nine requirements, including that any single occurrence of the benefit cannot be of a value greater than \$25, and all benefits must be made available only on the hospital campus.
- Fair market value compensation. If it is a percentage fee, it cannot be based on revenue or collections, and if it violates the antikickback laws, it is out.
- Compliance Training. Hospitals can provide free compliance training to local physicians, if it is provided in the local area, and the training relates to a compliance program or compliance with federal laws.
- Indirect Compensation Arrangements. Certain indirect compensation arrangements may now be acceptable, provided only fair market compensation is involved, compensation does not vary based on the volume or value of referrals, the agreement is generally in writing and reasonable, and it does not violate the antikickback laws. This new exception shows promise, but may be modified.
- Academic Medical Centers. Recognizing that the relationships in academic medicine just do not fit in the proposed Stark exception framework, CMS has created a new exception just for academic medical centers. This is an important new exception, even if the physician compensation criteria may prove troublesome.

### **WHAT IS THE EFFECTIVE DATE?**

The Stark II, Phase I rules were published on January 4, 2001, with a one-year delayed effective date. During the period of delay, President Bush put in place an across the board delay in the effective date of pending regulations. It is likely that CMS clarification will be required, but the regulations could be effective as early as January 4, 2002. However, they could also be effective on March 4, 2002, or even later if further delays are put in place.

### **BUT WHAT ABOUT ENFORCEMENT?!**

While as of the date of this update there appears to be no direct government enforcement initiative related to the Stark laws, there have been, and there are numerous pending "qui tam" private actions, some of which have been joined by the government. Technically, these cases are being brought under the False Claims Act, with the false claim being that the arrangement involved a financial arrangement that was not excepted under Stark.

- McLaren. A case out of Michigan, where the basis of the claim is above market lease rates on a lease of space by a hospital from physicians.
- Averbach. A case based on improper payments to physicians in a group practice, brought by a member of the group, alleging that group physicians were paid a direct percentage of their lab referrals.

In 2000, government officials disclosed that more than 50 cases were pending across the country, based, at least in part, on claimed violations of Stark.

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