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## On the Front Lines

# What Do Compliance Officers Need to Know About the Stark II Final Regulations?

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*Almost three years, to the day, after the "Proposed Stark II" regulations were promulgated HCFA published on January 4, 2001 "Phase I" of the Stark II Final Rule, which addresses the physician self-referral law in the* Federal Register *on January 4, 2001.*[1] *Given the extent to which this law affects healthcare organizations' ability to enter into financial relationships with physicians, this regulatory initiative has considerable implications to healthcare companies and their efforts to remain in compliance with the law. In this On the Front Lines feature, attorneys from Epstein Becker & Green, P.C. offer compliance officers an approach on how to respond to these new regulations.*

Over the next few months, healthcare executives, corporate compliance officers, in-house counsel, and healthcare professionals, will be inundated with articles and educational programs that address the substantive nuances of the various issues addressed in the Stark II final regulations.[2] However, after reading these articles and participating in these programs, many compliance officers may still be left with the questions "What impact does this rule have on my organization's compliance program?" and "What do I need to do?" This article sets forth several recommendations on actions that all corporate compliance officers should take in addressing how these new regulations affect their compliance program efforts.

**Overview of the Law.** The Stark law prohibits physicians with a financial relationship with an entity from referring Medicare (and to some extent Medicaid) patients to that entity for "designated health services," absent satisfaction of a specific statutory exception. On August 15, 1995, HCFA published final regulations under an earlier version of the Stark law, which only addressed clinical laboratory services. Additional designated health services were added to the Stark provisions in 1993 (*e.g.*, inpatient and outpatient hospital services, radiology ser-

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vices, durable medical equipment). On January 9, 1998, HCFA published proposed regulations addressing the aspects of the Stark law that were not addressed otherwise in the August 1995 final rule.

The *Final Rule*, which provides for a 90-day comment period, becomes effective January 4, 2002 (except for one provision of the regulations that addresses home health agency referrals, which becomes effective February 5, 2001). Phase I addresses only certain portions of the Stark law, in particular the nature of the referral prohibition, certain exceptions, and definitions of the key terms of the statute. In the preamble to the *Final Rule,* HCFA states that it expects to publish in the near future Phase II, which addresses the remaining aspects of the Stark Law, and responds to public comments on the issues raised in Phase I.[3]

**Step 1: Assess Your Physician Financial Relationships.** As a first step, compliance officers should begin working with those individuals within their organizations who are responsible for negotiating and approving financial arrangements with physicians (*e.g.*, legal advisors and members of senior management) to determine the types of financial relationships entered into with physicians and the general terms of those arrangements. Although it may be difficult for compliance officers to obtain a full listing of each and every financial relationship entered into with physicians who are in a position to refer patients, it is important that compliance officers understand the categories of ownership interests and compensation arrangements that the entity has with physicians. Key questions to answer include:

- Does the entity have any joint venture arrangements with physicians?
- Does the entity employ physicians and, if so, what is the structure of their salary?
- Does the entity lease office space or equipment from or to physicians?
- What type of marketing activities does the organization engage in with physicians (*e.g.*, Do sales and marketing personnel conduct meetings during a meal for which the physician does not pay? Does the entity send physicians gifts during the holiday season?)?

**Step 2: Develop a Schematic of the Company/ Entity.** To conduct an analysis of physicians' financial relationships under the Stark law, it is necessary that the reviewer have an exact understanding of the healthcare entity's corporate structure. In other words, does the healthcare entity have any subsidiaries and/or affiliates. Although a healthcare organization's corporate structure always has been important when analyzing financial relationships under the fraud and abuse laws, it is important that compliance officers and their legal advisors revisit this corporate structure because HCFA has:

(i) modified many of its previous positions on indirect financial relationships to apply to arrangements that previously had been outside the purview of the Stark law;

(ii) adopted a new exception for indirect compensation arrangements; and

(iii) defined the phrase "indirect compensation arrangements" to require that an analysis be conducted of the chain of financial relationships between the healthcare entity receiving the physicians' patient referrals and the physician or the physician's family member.

Therefore, even though compliance officers may not be responsible for conducting an evaluation of the permissibility of the actual financial arrangements, we recommend that compliance officers either create and/or obtain a diagram setting forth the different entities associated with the designated health services provider. This will serve as a useful tool in understanding whether the statute is implicated.

**Step 3: Identify Coding Experts.** The Final Rule defines the designated health services (*i.e.*, clinical laboratory services, physical therapy, occupational therapy, radiology and certain other imaging services and radiation therapy services) and includes lists of CPT and HCFA Common Procedure Coding System codes as an addendum. To determine whether the Stark law is implicated, compliance officers should review the lists of codes with the relevant personnel within their organization (*i.e.*, coding experts) to determine whether the organization bills for these types of services and procedures.

**Step 4: Determine which Aspects Are Deserving of Comments.** Based upon the types of financial relationships your organization may have with physicians, corporate compliance officers should coordinate with their legal advisors and examine the impact the Final Rule has on these arrangements We strongly encourage corporate compliance officers to take an active role in determining the extent to which their healthcare organization should submit comments on one or more particular issues.

**Step 5: Review Policies on Financial Relationships with Physicians.** After reviewing the types of financial relationships your organization may have with physicians and based upon the impact these new regulations have on these types of financial relationships, we suggest that compliance officers work with the appropriate individuals in their organizations to review and revise the organization's corporate compliance policies on financial relationships with physicians. For example, the Final Rule defines the phrases "indirect ownership or investment interest" and "indirect compensation arrangement" to include a "knowledge" element that requires providers in possession of facts that would lead a reasonable person to suspect the existence of an indirect financial relationship to take steps to determine whether such

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an arrangement exists and whether an exception applies. As a result, compliance officers, in consultation with their in-house legal or other appropriate individuals, should ensure that their organizations' compliance policies address this knowledge requirement. Although the Final Rule does not become effective until January 4, 2002, depending upon the degree of changes that are required and the process by which modifications to compliance program policies must be approved by the organization, compliance officers should be mindful that January 2002 will "be here before you know it."

**Step 6: Develop Compliance Training Modules.** Given that Phase I of the final regulations is over 100 pages in the *Federal Register* and as it addresses a multitude of issues, conducting education sessions for all employees, physicians and other healthcare professionals about the Stark II requirements will not be an easy task. Nevertheless, we suggest that compliance officers begin to evaluate the process by which they will educate the personnel on this new regulatory initiative. Specifically, we recommend that training activities be directed to any personnel who are responsible for working with physicians.

As with any educational activity, compliance officers should explain the new requirements in clear, easy to comprehend language with concrete examples, including, when appropriate, the use of charts, diagrams, flow charts, and frequently asked questions. As the employee charged with safeguarding the compliance of an organization, compliance officers should use all educational tools at their disposal to ensure that the decisionmakers within their organization are aware of what they can and cannot do under the Stark law as well as what they should do if they identify a potentially improper financial relationship.

Specifically, we suggest that training activities use examples of the types of activities that are and are not permitted under the regulations. For example, when explaining to hospital personnel that HCFA has established a new exception that allows hospitals to provide members of the medical staff with certain benefits, illustrate this exception by explaining that it is permissible for a hospital to provide physicians with free parking when they are on-call and free computer/Internet Access while the physician is on the hospital's campus. In addition, training should emphasize that employees do not need to understand all of the laws' nuances, but provide a process by which the employees can raise questions and get answers.

**Conclusion.** Phase I of the final regulations contains both good and bad news for healthcare organizations. The good news is that HCFA has attempted to make it easier for some types of financial relationships to be excepted from the purview of the statute by paring down some of the requirements that had been included in the 1998 proposed rule. The bad news is that the *Final Rule* has adopted a host of restrictions on financial relationships between healthcare organizations and physicians that may not have been evaluated previously under the Stark law. Therefore, we suggest that compliance officers begin to take the steps outlined above to ensure that their organizations comply with the Stark II requirements.

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1 42 U.S.C. § 1395nn; *see also* 63 Fed. Reg. 1,659 (Jan. 9, 1998) and 66 Fed. Reg. 856 (Jan. 4, 2001). The federal self-referral law is often referred to as the "Stark Law" after Congressman Pete Stark, who introduced and strongly supported the statute. The first version of the Stark law, which prohibited physicians from ordering only clinical laboratory services for Medicare patients from an entity with which the physician had a financial relationship, is often referred to as "Stark I." The expansion of the Stark law to the other designated health services is often referred to as "Stark II."

2 We recommend, however, that readers review the article *Final Stark II Regulations: More Good News Than Bad* which appeared in the January 15, 2001 edition of CCH Healthcare Compliance Letter. In addition, HCFA has published "Questions and Answers" to the Final Regulations on its Medicare Learning Network web site (www.hcfa.gov/medlearn/faqphys.htm).

3 Upon taking office, the Bush Administration temporarily postponed the effective date of regulations that were published in the *Federal Register* at the end of the Clinton Administration and which have not yet taken effect until the regulations are reviewed by a department or agency head. This action could affect these regulations.