Two Years in the Making: Phase I of the Stark II Regulations Arrive

On January 4, 2001, two years after publishing proposed regulations interpreting the federal physician self-referral laws commonly known as "Stark II," HCFA issued "Phase I" of the final regulations interpreting Stark II’s prohibitions. In Phase I, HCFA has made significant changes to the Stark II regulations originally proposed in January 1998. In light of these significant changes and HCFA’s attempt to respond to health care community concerns regarding Stark II’s impact, the effective date of the regulations has been delayed until January 4, 2002 (except in the case of certain physician home health plan of care certification regulations which go into effect on February 5, 2001).

Stark II
Subject to certain enumerated exceptions, Stark II generally prohibits physicians from referring Medicare or Medicaid beneficiaries for the provision of "designated health services" to entities with which the physicians have a "financial relationship." In addition, entities which receive such prohibited referrals may not receive Medicare or Medicaid reimbursement for the services provided to the referred beneficiaries. As defined by Stark II, "designated health services" include a range of services such as clinical laboratory services, radiology services, durable medical equipment, home health services, hospital inpatient and outpatient services and other enumerated services. The term "financial relationship" is broadly defined to include direct and indirect ownership interests and compensation arrangements.

Stark II’s prohibitions have broad impact on many common arrangements in the healthcare world. Therefore, HCFA’s interpretation and enforcement of these prohibitions are of significant interest to the healthcare community.

Two "Phases"
Given the complexity of the regulations, HCFA divided the regulatory process into two phases. Phase I, which was issued January 4, implements the general Stark II prohibitions, sets out definitions of Stark II’s major terms including definitions for "referral," "financial relationships" and "designated health services" and describes several Stark II exceptions including those related to physician services, in-office ancillary services and prepaid health plans.

Phase II will cover the remaining Stark II exceptions, including those related to professional services arrangements and lease arrangements. In addition, Phase II will review Stark II’s reporting and penalty provisions. Finally, Phase II will include any changes to Phase I made as a result of public comments received during the Phase I 90-day comment period which expires on April 4, 2001.

Therefore, we do not anticipate that Phase II will be issued before (and probably much after) mid-Summer, 2001.

Timing
In recognition of the substantial changes included in the newly issued regulations, HCFA is generally delaying their effective date for 1 year "to allow individuals and entities engaged in business arrangements affected by the [regulations] time to restructure those arrangements to comply with the provisions of the [regulations]...." Nevertheless, HCFA notes that the Stark II statutory prohibitions remain in full force and effect. In addition, until the effective date of these regulations, the 1995 Stark I regulations relating exclusively to clinical laboratory services are also in full force and effect.

"Bright Line Rules Which are Easily Applied"
According to HCFA’s commentary accompanying the regulations, provider concern was, in large part, the cause for the delay in publication – as well as the one year delay in the regulations' effective date to January 2002.

In response to the proposed regulations published in January 1998, many commentators stated that the proposed regulations were not in keeping with the manner in which physicians deliver services and the manner in which they relate to one another. Some commentators stated that the provisions of the proposed regulations imposed unnecessary and costly burdens on physicians that "would harm patient access to healthcare.
facilities and services, with no apparent public benefit." It has been universally noted in the provider community that the regulations' terms and limitations were far from clear.

As advertised by HCFA, the final regulations include "bright line rules that are easily applied, while providing the health care industry with as much flexibility as possible." In some respects, these final Stark II regulations vary significantly from those published two years ago. HCFA maintains that the regulations have been greatly simplified and their impact on "common physician group governance and compensation arrangements" has been minimized. In some areas greater clarity appears to have been achieved; in other areas it has not.

**Phase I: The Highlights**
The Phase I regulations differ significantly from the January 1998 proposed rule in several major respects which include the following:

- Clarification of the concept of "indirect financial relationship" and creation of a new exception for indirect compensation arrangements.
- Substantial broadening of the in-office ancillary services exception by easing the criteria for qualifying as a group practice.
- Allowance of shared facilities in the same building where physicians conduct their general medical practices.
- Exclusion of services personally performed by the referring physician from the definition of "referral."
- Addition of a new "risk-sharing" exception for commercial and employer-sponsored managed care plans.
- Interpretation of the "volume or value" standard as permitting fair market value unit-of-service or unit-of-time based payments.
- Creation of a new exception where designated health services are furnished by entities that did not know of or have reason to suspect the identity of the referring physician.

**Analysis in Coming Client Alerts**
In order to fully address the impact of the new Stark II regulations, we will be issuing over the next several weeks a series of Client Alerts focusing on specific aspects of the regulations. These Client Alerts will discuss common physician contract, compensation and ownership arrangements and how they are affected by the regulations. In addition, we will examine how the new regulations may shape and direct future enforcement of Stark II's prohibitions as well as other Medicare and Medicaid laws, including the Civil False Claims Act, the Antikickback Statute and the Civil Monetary Penalties Law.

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