Health Law

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Stark II Phase II

On July 26, 2004, the second phase of the Stark II law¹ (The “Phase II rule”) was published by the Centers for Medicare and Medicaid Services (“CMS”). This long awaited second phase augments the Stark II ban on physician referrals to healthcare entities with which they have financial relationships. While much of the this newest round of regulations is either a simple restatement of the Phase I rule from January of 2001 or derived from the original Stark I regulations published in 1995, several key changes have been made and CMS utilizes Phase II to provide a response to public comments and criticism of the three-year-old Phase I.

What Is Stark?

To understand what this newest round of Stark laws does, one must understand what the Stark laws are and why they are so important to healthcare regulation. The original Stark self-referral prohibition was enacted in 1989 with the purpose of limiting improper referrals of patients by physicians who utilize these referrals for financial gain. The self-referral ban (Stark I) went into effect on January 1, 1992. As a general summary, this section prohibits physicians from referring Medicare beneficiaries for clinical laboratory services to entities with which they, or members of their immediate family, have a financial relationship. It also prohibits entities from making a claim for payment under the Medicare program for clinical laboratory services furnished pursuant to a prohibited referral.²

In light of the success of Stark I, amendments were subsequently made which went into effect on January 1, 1995, and published in 1998. Known as Stark II, these newer regulations prohibit physician referrals of Medicare beneficiaries to entities with which they, or members of their immediate family, have a financial relationship for designated health services (“DHS”) (DHS include: clinical laboratory services; physical therapy services; occupational therapy services; radiology services (including MRI, CAT scans, and ultrasound services); radiation therapy services and supplies; etc.). This Stark II ban also prohibits entities from making a claim for payment under the Medicare or Medicaid programs for the provision of a DHS furnished pursuant to a prohibited referral.²

What Was Phase I?

The final regulations for the Stark II laws were issued in 2001. These regulations address separate provisions and amendments to the Stark I laws. Therefore, the magnitude of the task required CMS to operate these refinements in separate phases. Phase I³ of Stark II addresses the general prohibition on physician referrals and those general exceptions that are applicable to both ownership or investment interest and compensation arrangements. In addition to implementing the general prohibition on referrals with respect to Medicare beneficiaries, Phase I also provides the definitions for Stark II, although it fails to address exceptions that are only applicable to ownership or investment interests and the exceptions that are only applicable to compensation arrangements. The Phase I prohibitions only
apply to referrals of Medicare beneficiaries. It was expected that Phase II would expand on the scope of these prohibitions. Phase I’s shortcomings were subsequently noted by CMS and critiques of Phase I were taken into account during the drafting of the newer Phase II provisions.

What Is Stark II Phase II (Highlights)?

With Phase II of Stark II tipping the scales at well over 200 pages, certainly a brief mention of the highlights is most appropriate. Generally, Phase II of the final Stark II regulations addresses the provisions in the Stark law not addressed in Phase I of the rule making process and covers additional regulatory definitions, new regulatory exceptions, and responds to public comments on Phase I regulations. Few surprises resulted from the drafting of this newest section. However, in one surprise, CMS opted to not address Medicaid covered services within this round of rule making, rather, it reserved rule making for Medicaid covered services for future versions (Phase III). Phase II creates an exception for certain arrangements that have fallen out of compliance with other exceptions, creates an exception for intra-family referrals, modifies the group practice definition to address issues faced by noncomplying group practices, and clarifies the lease (equipment and office) provisions. Below is a brief list of some highly relevant changes reported in Phase II.

Compensation for Personal Services Arrangements

Under the general Stark provisions, compensation to physicians must be set in advance of any agreement between parties. Phase II specifies that the agreement will be determined to have been “set in advance” if a formula for compensation is set forth before compensable services are undertaken.

One-Year Term Requirement

Phase I regulations required that service and lease arrangements have a term of at least one year. In Phase II, CMS revised the regulations to specify that there is no violation of the one-year term requirement where early termination occurs, so long as the parties do not enter into the same or substantially the same arrangement during the remainder of the original term.

Group Practice Definition

The definition of “Group Practice” has significant meaning to any group of physicians that wish to take advantage of the in-office ancillary services and physician services exceptions. Although no major changes were made to the Group Practice definition in Phase II, slight modifications were made in order to provide for more flexibility for group practice compliance with the regulations.

Physician Recruitment Exception

The Phase II regulations modify the physician recruitment exception to allow recruitment payments for physician relocation subject to the following conditions: (1) the geographic area served by the hospital consists of the lowest number of contiguous zip codes from which the hospital draws at least 75% of its inpatients; (2) a physician is deemed to have relocated to a hospital’s geographic area if the physician has relocated the site of the physician’s practice a minimum of 25 miles, or if at least 75% of the physician’s revenues for professional services provided to patients are derived from services provided to new patients; (3) residents and physicians who have been in medical practice less than one year are not considered to have an established practice and, therefore, are not eligible under the exception even if they do not relocate; and (4) recruitment payments made through existing medical groups, rather than directly to the recruited physician, are permitted as long as the remuneration, less actual costs, is passed on to the recruited physician.
Academic Medical Center Definitions

Academic Medical Centers under an exception to Phase I, were specifically composed of an accredited medical school, an affiliated faculty practice plan, and one or more affiliated hospitals. This prior definition of an “academic medical center” was deemed by CMS to be overly restrictive. Therefore Phase II expands this definition to cover both accredited medical schools and accredited academic hospitals. Phase II now defines accredited academic hospitals as those that sponsor four or more approved medical education programs. Additionally, these academic hospitals may serve as the affiliated hospital for purposes of comprising an academic medical center.

Master List for Personal Services Arrangements

To augment the Phase I requirement that personal services contracts and arrangements cover all services furnished between physician and immediate family members, Phase II now requires that each personal service contract either incorporate the other agreements by reference, or cross-reference a master list of contracts that is maintained centrally and updated in a manner that preserves the historical record.

Office Space and Equipment Rental Exceptions

Several changes were made to the specific provisions concerning physician leasing arrangements. Phase II modifies the one-year holdover period for lease agreements, now permitting month to month holdovers for up to six months. Additionally, CMS revised the exclusive use requirement to allow for subleasing of office space and equipment. This provision was also modified to cover any type of operating or capital lease in addition to operating leases.

Additional Phase II Exceptions

A number of new Regulatory Exceptions were also added under Phase II. These changes cover: new exceptions for professional courtesies, arrangements under Stark that meet the conditions of the anti-kickback safe harbors, charitable donations by physicians, allowance for temporary noncompliance, and community-wide health information systems exceptions. Additionally, further clarifications were made as to what qualifies as an “isolated transaction,” what restrictions physicians must adhere to for purposes of employment and managed care contracts, and what is covered under the “same building” test for physician referrals.

Penalties Under Stark II

While a significant (and sometimes confusing) list of prohibited services and arrangements now exists under the several Phases of Stark II, and with a potential Phase III not out of the question, every practitioner should be aware that violations of Stark II carry significant penalties. The civil money penalty is a maximum of $15,000 for each service. While this may not in itself be entirely prohibitive, under the Stark laws, the physician must also refund any amounts billed in violation of the law, and physicians who violate Stark face potential exclusion from Medicare.

Conclusion

This article serves only to highlight the new material and to cover the newest phase of Stark as it relates to prior versions of the law. As a word of caution, any attorney advising their clients regarding the coverage and extent of the Stark laws should carefully review and scrutinize the applicable statutes. Additionally, the laws and regulations do not replace other relevant statutes and regulations (Federal Anti-Kickback Statute and any State laws concerning self-referrals). Therefore, attorneys...
should be fully aware of all aspects of the applicable healthcare laws before advising clients on the ever-changing face of Stark regulation.

Endnotes

1 60 Fed. Reg. 16053 to 16146 (March 26, 2004).
2 42 U.S.C § 1395.

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