

The New Stark Rules: What Does Stark II Phase III Mean for Healthcare Providers?

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Senator Pete Stark, sponsor of the Physician Self-Referral Law, was recently quoted as saying he wished he had never sponsored the law due to its now complex requirements and iterations imposed by the Centers for Medicare & Medicaid Services. The new Stark II Phase III rules further muddy the waters. This article reviews the basic Stark prohibitions and provides an overview of Stark II Phase III.

Key words: Stark; self referral; Stark III; Phase III; Physician Fee Schedule.

On September 5, 2007, the Centers for Medicare & Medicaid Services (CMS) published the long-awaited third installment in its rulemaking process under the federal physician self-referral prohibition commonly known as the “Stark law.” Stark II Phase III (Stark III) is the final phase of the CMS rulemaking process related to the Stark law. All parts of the new regulations were to be effective December 4, 2007. However, on November 15, 2007, CMS delayed the effective date of the so-called “stand in the shoes” provisions of Stark III for academic medical centers and nonprofit integrated health systems until December 4, 2008. All other provisions of the regulations became effective December 4, 2007.

While CMS states that the purpose of the Stark III rules is to reduce the regulatory burden on the healthcare industry through CMS’ interpretation and modification of previously promulgated exceptions to the Stark Law’s general prohibition on referrals, Stark continues to be one of the most complex and confusing laws impacting medical groups. Experienced healthcare attorneys and government regulators continuously debate the meaning of Stark, and no healthcare provider should contemplate any arrangement potentially implicating Stark without the guidance of knowledgeable legal counsel. Further complicating the new

Stark III rules are the 2008 Physician Fee Schedule revisions related to the physician self-referral rules.

STARK BASICS

The original Stark self-referral prohibition was enacted in 1989 with the purpose of prohibiting physicians from referring patients for laboratory services to entities in which the physicians had a financial interest. The self-referral ban was referred to as “Stark I” after Rep. Pete Stark (D-CA), who introduced the legislation. In 1993, Stark was expanded to cover additional healthcare services considered to be particularly susceptible to overutilization as a result of physician financial interests and to apply in part to Medicaid beneficiaries. The 1993 amendments are referred to as “Stark II” and went into effect on January 1, 1995. The regulations for Stark I and Stark II were promulgated in three phases by CMS. Phases I, II, and III of the Stark regulations are intended to be co-dependent and read together.

The Stark law prohibits a physician from making referrals for Medicare-covered designated health services (DHS) to an entity with which the physician or an immediate family member has a “financial relationship,” unless the referral fits in an exception to the ownership and compensation arrangement prohibitions. This general prohibition applies to referrals for Medicare-covered DHS made by a physician to any hospital, freestanding imaging center, or independent clinical laboratory with which that physician has a compensation arrangement. Stark also prohibits entities from making a claim for payment by

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Medicare for the provision of DHS furnished pursuant to a prohibited referral.

DHS include: clinical laboratory services; physical therapy services; occupational therapy services; radiology services (including MRI, CT scans, ultrasound services, and nuclear medicine); radiation therapy services and supplies; durable medical equipment (DME) and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospitalization services.

The Stark law and regulations provide five general exceptions to the ownership and compensation prohibitions. Each exception has numerous elements, and strict compliance with all elements of an exception is required. The general exceptions to Stark are as follows:

1. Physician services
2. In-office ancillary services
3. Prepaid plans
4. Intra-family rural referrals
5. Academic medical centers

In addition, many states have “mini” Stark laws that prohibit or restrict physician self-referrals based on state law. Any Stark analysis must include an analysis of both the federal and state laws regarding physician self-referral.

PENALTIES FOR VIOLATIONS OF STARK

The Stark law establishes a number of sanctions for violations of its provisions. These sanctions range from denial of payment, required refunds to patients, civil money penalties of up to \$15,000 for each violation, exclusion from further participation in the Medicare and Medicaid programs, and civil money penalties of up to \$10,000 for each day in which the DHS entity fails to report required information. In addition, separate civil money penalties may be imposed.

The Stark law imposes civil money penalties of up to \$100,000 for any arrangement or scheme that the physician or DHS entity knows or should know has a principal purpose of ensuring referrals by the physician to the particular DHS entity, which, if the physician directly made referrals to the DHS entity, would violate the Stark law. Exclusion from the Medicare program is an additional penalty that the Office of the Inspector General may impose for entering into a circumvention scheme.

PHASE III HIGHLIGHTS

This article provides an overview of the highlights of Phase III and identifies common issues impacting physician group practices. Because the Stark III regulations including the preamble are several hundred pages long, it is impossible to address all aspects of Stark III in this article. However, some of the more significant provisions

of Phase III affecting physician group practices are described below. Other Stark III provisions are listed for reference. Given the complexity and mounting vagueness with each Phase of regulations, any physician or physician group providing services to patients that could be construed as a physician self-referral must consult an experienced healthcare attorney before entering into any arrangement governed by Stark or any state law pertaining to self-referral.

The more significant provisions of Stark III include:

1. Physician recruitment exception is relaxed. The most significant change to the Stark regulations contained in Phase III is the change to the physician recruitment exception. The physician recruitment exception protects certain compensation that is provided by a hospital to a physician as an inducement for the physician to relocate his or her medical practice into the “geographic area served by the hospital.” Several changes were made to the exception as follows:
 - a) Group practices may now impose practice restrictions if they do not “unreasonably restrict” the recruited physician’s ability to practice in the “geographic area served by the hospital.”
 - b) Rural hospitals have a new special option in determining the “geographic area served by the hospital.”
 - c) Groups in a rural area or health professional shortage area may now recruit a physician to replace a retired, deceased, or relocated physician by allocating the costs attributed by the recruited physician based upon: (1) the actual additional incremental costs; or (2) the lower of a per capita allocation or 20% of the practice’s aggregate costs.
 - d) Rural hospitals may now recruit physicians into an area outside of the “geographic area served by the hospital” if the Secretary of the Department of Health and Human Services determines in an advisory opinion that the area has a demonstrated need for the physician.
 - e) The recruitment exception now applies to rural health clinics in the same manner as it applies to hospitals and federally qualified health centers.
 - f) Recruited physicians are now exempt from the relocation requirement if they were employed full time by a federal or state bureau of prisons (or similar agency), the Departments of Defense or Veterans Affairs, or facilities of the Indian Health Service, if the physician did not maintain a separate private practice in addition to the full-time employment. CMS also clarified that the provisions of the recruitment exception that apply to recruitment arrangements involving physicians who join an existing practice do not apply when the recruited physician is just co-locating or sharing space with an existing practice and does not join the practice.

2. “Stand in the shoes” provisions are added to provisions addressing compensation arrangements. Physicians stand in the shoes of their group practices. Phase III includes new provisions addressing compensation arrangements in which a group practice (or other “physician organization” as newly defined in Phase III) is directly linked to the physician in a chain of financial relationships between the referring physician and a DHS entity. For purposes of determining whether a physician has a direct or indirect financial relationship with a DHS entity to which the physician refers, under Phase III, the physician will stand in the shoes of his or her physician organization. A physician who stands in the shoes of his or her physician organization is deemed to have the same compensation arrangements as the physician organization itself. “Physician organization” is defined to include group practices, professional corporations, and physician practices. In addition, physicians who contract with a physician organization, but are not employees or members of the physician organization also stand in the shoes of the organization. On November 15, 2007, CMS delayed the application of this stand in the shoes provision of the Stark Phase III Rules for academic medical centers and nonprofit integrated health systems until December 4, 2008.
3. Definition of “physician in group practice” is tightened. Under Stark III, an independent contractor physician must furnish patient care services for the group practice under a direct contractual arrangement with the group, and not between the group practice and another entity, such as staffing entity. An independent contractor physician is only considered a physician in the group practice when he or she is performing services in the group’s facilities, and thus has a true nexus with the group’s medical practice. The definition of “physician in the group practice” has been clarified to include only members (owners or employees) and independent contractors, and not other types of employment arrangements, such as staffing arrangements.

Other provisions of Stark III include:

 - Safe harbor for fair market value is eliminated.
 - Physician-furnished DME is clarified.
 - Group practice definition is modified to clarify how productivity bonuses can be determined.
 - In-office ancillary shared services arrangement requirements are clarified.
 - Personal service arrangement exception is expanded to permit a holdover for up to six months on the same terms as the original agreement, where the term of the personal services agreement has expired.
 - Professional courtesy discount exception is revised.
 - Academic medical centers exception is clarified.
 - Rural referral exception is modified.
 - Security interest in equipment sold to a hospital is now considered a compensation arrangement and

no longer strictly prohibited.

- Exception for retention payments in underserved areas is modified.
- Compliance training exception is expanded.
- Fair market value exception is expanded to cover payments by a physician.
- Cure is permitted for inadvertent excess non-monetary compensation.

PHYSICIAN FEE SCHEDULE REVISIONS RELATING TO THE PHYSICIAN SELF-REFERRAL RULES

On November 1, 2007, CMS revised the Medicare Physician Fee Schedule (Physician Fee Schedule) pertaining to the physician self-referral rules. A significant part of those revisions includes an anti-markup provision that will have a material impact on physician practices. As a general rule, the anti-markup provision prohibits markups when billing for technical and professional components of diagnostic tests that are ordered by the billing physician or other supplier (or ordered by a party related by common ownership or control to such billing supplier) where: (1) the technical or professional component is outright purchased; or (2) the test is performed at a site other than the office of the billing physician or other supplier.

CMS defines “offices of the billing physician or other supplier” as medical office space where the physician/supplier regularly furnishes patient care, and, in the case of a Physician Organization (defined in the rule), is used to provide substantially the full range of patient care services provided generally by the Physician Organization.

When the anti-markup rule applies to a particular arrangement, only the *lowest* of the following three billing methods can be utilized to bill for the tests: (1) the diagnostic testing provider’s net charge to the billing physician or other supplier; (2) the billing physician or other supplier’s actual charge; or (3) the Medicare fee schedule amount for the test that would be allowed if the diagnostic testing provider billed directly. CMS has left “net charge” determinations up to the billing entity, but has stated that overhead, including actual cost of equipment or lease of space as part of the charge, cannot be included in any calculation of net charge.

Arrangements that have passed the Stark test in the past must be reexamined to ensure continued compliance with the Stark III as well as the recent Physician Fee Schedule revisions.

CMS acknowledges that it has been receiving many questions on when and how the anti-markup rule applies in various situations. CMS also indicated that a list of

frequently asked questions would be posted “soon” on its Web site, but could not confirm when. While uncertainty with regard to the anti-markup rule may continue, CMS is adamant about the fee schedule revisions taking effect on the scheduled effective date—January 1, 2008.

CONCLUSION

Although these new Stark III Rules are sometimes labeled “final,” more regulation pertaining to physician self-referral is anticipated. Additional regulation is anticipated with respect to in-office ancillaries and “under arrangements” relationships between physician groups and

hospitals. The Stark law and the Stark I, II, and III regulations are complex and not easily understood. In addition, they interface with other regulations, such as the Physician Fee Schedule. Every arrangement that potentially implicates any phase of Stark must be carefully analyzed and must fit completely within an exception to Stark’s broad prohibition on self-referral. In addition, arrangements that have passed the Stark test in the past must be reexamined to ensure continued compliance with the Stark III as well as the recent Physician Fee Schedule revisions. The consequences of noncompliance with Stark are significant; and unlike the Fraud and Abuse prohibitions, Stark is not intent-based, so ignorance of the law is no excuse. ■