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If you have questions regarding this bulletin, please contact Michael E. Reed (312) 609-7428 or any other Vedder Price attorney with whom you have worked.

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HCFA RELEASES PROPOSED STARK II REGULATIONS

On January 9, 1998, the Health Care Financing Administration ("HCFA") released the much-anticipated proposed regulations for Section 1877 of the Social Security Act (42 U.S.C. § 1395nn). 63 Fed. Reg. 1659 (Jan. 9, 1998). Named after the law's major sponsor, Pete Stark, Section 1877 is commonly known as "Stark." The proposed regulations will supplement existing Medicare regulations which implement Stark's prohibition against certain types of physician referrals. Through these proposed regulations, HCFA also seeks to clarify certain aspects of the Stark law. Notably, the proposed regulations add two new exceptions to Stark. HCFA will receive comments on the proposed regulations until March 10, 1998.

Background

In response to concerns over physician self-referral (i.e., referrals to entities in which physicians or their family members have a financial relationship), Congress added section 1877 to the Social Security Act ("Stark I") on December 19, 1989. Stark I prohibited physician referrals to clinical laboratories in which a physician (or an immediate family member of the physician) had a financial relationship, and proscribed clinical laboratories from submitting a Medicare or Medicaid claim for services furnished pursuant to a prohibited referral. Additionally, Stark I: 1) mandated refund of any amount collected from an individual as a result of a billing for an item or service prohibited under a prohibited referral;
2) imposed certain reporting requirements; and
3) provided for sanctions. Stark I also provided certain exceptions to the general prohibition against physician self-referrals for clinical laboratory services.

Congress significantly modified Stark I in 1993,

expanding it to apply to physician referrals for ten "designated health services" ("Stark II"). For Stark II purposes, the following services are deemed designated health services: clinical laboratory services; physical therapy; occupational therapy; radiology; radiation therapy and supplies; durable medical equipment ("DME") and DME supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics and orthotic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. With certain exceptions, Stark II prohibits a physician from making a referral to an entity for the furnishing of designated health services for which Medicare may otherwise pay, if the physician (or an immediate family member) has a financial relationship with that entity. Stark II also modified certain Stark I exceptions and added new ones.

On August 14, 1995, HCFA promulgated a final rule implementing Stark I's prohibition against physician self-referrals to clinical laboratories. Until recently, however, HCFA had not issued regulations to implement Stark II.

Proposed Stark II Regulations

The proposed Stark II regulations expand existing Stark I regulations to cover all designated health care services. The following discussion highlights significant changes and new interpretations made by HCFA to existing Stark I regulations.

Designated Health Services

In general, the proposed regulations define designated health services based on the definitions appearing under Part of Medicare. In some instances, however, HCFA deemed that deviation from the Medicare Part B definition of certain designated services was necessary to uphold the intent of Stark II.

Radiology Services

Under the proposed regulations, the definition of radiology services excludes all forms of "invasive" radiology. HCFA also excludes *screening* mammography from the definition of radiology services. The term radiology services does, however, encompass *diagnostic* mammography.

In addition, the proposed rule includes the physician's professional service component in the definition of radiology services. Traditionally, Medicare has treated a physician's professional radiology services as a separate and distinct service. Under the proposed Stark II rule, however, the definition of radiology services will now include the professional component since whenever a technical radiology service is over-utilized, the physician's radiological services also will be over-utilized.

The practical effect of this proposed change in the definition of radiology services is that, absent an applicable exception, a physician cannot refer Medicare patients to an imaging center if that physician (or an immediate family member of the physician) has a financial relationship with the radiology group that will interpret the images at the center. In the latter case, the physician would be prohibited from making a referral even though she had no direct financial relationship with the diagnostic imaging center itself.

DME

Under the proposed regulations, DME would exclude end-stage renal disease ("ESRD") equipment and supplies, including home dialysis supplies.

Prosthetics, Orthotics, and Prosthetic Devices

The proposed definition of prosthetic devices includes intraocular lenses and one pair of conventional eyeglasses or contact lenses subsequent to the insertion of an intraocular lens. Additionally, under the proposed rule, intraocular lenses implanted in an ambulatory surgery center ("ASC") would be covered under the ASC's payment rate. Any services covered under the ASC rate will be excluded from the Stark II referral prohibition under 42 C.F.R. § 411.355(d) (a regulatory Stark II exception that covers services furnished in an ambulatory surgical center).

Home Health Services

With respect to this designated health service, HCFA has taken the position that a home health agency owned by a hospital cannot meet the requirements of the Stark II "hospital ownership" exception.

In addition, the preamble indicates that HCFA intends to cross-reference in the Stark II regulations Sections 1814(a) and 1835(a) of the Social Security Act in order to reconcile the prohibitions under Stark II and these Sections which prohibit the certification of need for home health services by a physician with a "significant" ownership, contractual or financial interest in the home health agency that will provide the services. HCFA has indicated that since the exceptions listed under Sections 1814(a) and 1835(a) are superseded by Stark II, the agency will propose to eliminate them. Therefore, in the future, Stark II will most likely be treated as the sole regulatory authority governing referrals for home health services by physicians who have financial relationships with the entities providing those services.

Outpatient Prescription Drugs

The definition of this designated health service includes only drugs furnished to individuals under the Medicare Part B benefit and excludes drugs furnished by providers under Medicare Part A. This definition is limited to drugs that a patient is able to obtain from a pharmacy with a prescription. Also, HCFA would not include as outpatient prescription drugs certain pharmaceuticals furnished as part of dialysis treatment for ESRD patients.

Inpatient and Outpatient Hospital Services

Under the proposed Stark II regulations, "inpatient hospital services" includes inpatient psychiatric hospital services. Although rural primary care hospitals ("RPCHs") are not considered hospitals under Medicare for most purposes, the proposed rule includes in the definition of inpatient hospital services any inpatient service provided by an RPCH. In what may be a controversial decision, HCFA has decided to include lithotripsy in the definition of inpatient hospital services.

HCFA proposes to exclude from the definition of inpatient hospital services certain emergency services provided outside the United States. "Inpatient hospital services" also excludes dialysis furnished by hospitals that are not certified to provide ESRD services under Part U of 42 C.F.R. § 405.

Similar to the definition of inpatient hospital services, the definition of outpatient hospital services also will include

lithotripsy. Additionally, outpatient hospital services will include outpatient services furnished by a psychiatric hospital and RPCH services.

Referrals

The proposed regulations clarify the meaning of a referral within the Stark II context. Previously, HCFA had indicated that physicians and physician groups should refrain from making referrals to entities with which they have a financial relationship. Under the proposed regulations, only referrals for designated health services are prohibited. Therefore, referrals for non-designated health care services (or services not covered by Medicare or Medicaid) are not subject to Stark II prohibitions and sanctions. In addition, a physician generally may lawfully receive a productivity bonus for any non-designated health services the physician performs, or for designated health services performed pursuant to a referral made by another physician.

Ownership or Investment Interests

Under Stark II, an "ownership or investment interest" in an entity is defined to include an interest in an entity that holds an ownership or investment interest in any entity providing designated health services (e.g., a physician has an interest in a holding company, one of whose assets is an entity providing designated health services). Thus, HCFA has chosen to interpret ownership or investment interest to apply even to indirect ownership interests. Therefore, under the proposed regulations, a physician would not be able to escape Stark II liability by setting up a corporate structure consisting of multiple levels of ownership.

In-Office Ancillary Services

To qualify for Stark II's in-office ancillary services exception, the services must, among other things, be personally furnished by a referring physician or another physician in the same group practice, or be furnished by individuals who are "directly supervised" by one of these physicians. Under the Stark I regulations, "direct supervision" meant that the physician had to be present in the office suite and be immediately available to provide assistance and direction throughout the time the aide or technician rendered the services. That is, the physician would not be considered to be "directly supervising"

personnel if the physician left the office while the patient was being treated. Under the proposed regulations, however, a physician would be allowed to take brief, unexpected absences as well as routine absences of short duration (e.g., a lunch break) and still provide direct supervision for Stark II purposes.

Another requirement of the in-office ancillary services exception is that the service is supplied in a "building" in which the referring physician (or another physician who is a member of the same practice) furnishes physician services unrelated to the furnishing of designated health services. In its proposed rule, HCFA interprets "building" to mean one physical structure, with one address, and not multiple structures that are connected by tunnels or walkways. Further, the term "building," for Stark II purposes, comprises those parts of the physical structure that are used as office or other commercial space. Thus, the definition of building under the proposed Stark II regulations excludes mobile units (e.g., x-ray vans) parked in a building's garage from being deemed part of that building. As a result, mobile units might be disqualified for the in-office ancillary services exception.

Regarding the billing number requirement for in-office ancillary services, HCFA has taken the position that a group practice can have more than one billing number. This new interpretation would accommodate those group practices that have multiple provider numbers because they have multiple locations or operate in more than one state. Provided that certain statutory requirements are met, under the proposed regulations, a group may bill through an agent, if the agent bills for the group under the group's name and uses the group's billing number. A group would not be able to receive payment through a separate entity (one that is not wholly owned by the group) billing under its own right and under its own billing number, even if the payments ultimately constitute group practice revenues.

In response to concerns voiced by many physicians, under the proposed regulations, physicians may supply crutches to patients pursuant to the in-office ancillary services exception, as long as the physician sells the crutches at cost.

Group Practices

When a group of physicians qualifies as a "group

practice," the group may qualify for a number of Stark II exceptions specifically designed to accommodate groups (e.g., the in-office ancillary services exception). HCFA has proposed a number of significant changes to the definition of "group practice." For instance, the proposed rule redefines "members of a group" to include not just physician partners, but physicians with any other form of ownership interest in the practice (including physicians whose ownership interests are held by their individual professional corporations).

To qualify as a "group practice," a group must demonstrate that each physician member furnishes substantially the "full range of patient care services" that the physician routinely furnishes (e.g., consultation and medical care) through the joint use of shared office space, facilities, equipment and personnel. At present, "patient care services" is defined as any task performed by a member that addresses the medical needs of specific patients. Under the proposed regulations the term "patient care services" has been redefined to apply not only to physician activity that addresses the medical needs of specific patients, but also to activities that address the needs of patients in general, or the practice itself. This new definition should make it easier for a physician group to qualify as a "group practice." Note, however, that time spent teaching or doing outside research would not qualify as a patient care service under the proposed rule.

The proposed Stark II regulations make it easier for physician groups to qualify as a group practice in another important way: HCFA has proposed to exclude independent contractors from the definition of group members. This definitional change is significant because to qualify as a "group practice," at least seventy-five percent (75%) of total patient care services of all the members must be furnished by or through the group's members. By excluding independent contractors from the definition of group members, groups should find it easier to qualify as a "group practice." The exclusion of independent contractors from the definition of group members has a significant drawback, however: independent contractors cannot provide the requisite direct supervision for designated health services under the in-office ancillary services exception because only group members can provide supervision for purposes of this exception.

Assuming a group does qualify as a "group practice," the proposed regulations would allow the group to have more than one central location. This is significant because it means that group practices do not have to provide all designated health services at one location. The new regulations also allow a group practice to furnish one kind of ancillary designated health service at one location, and a different ancillary designated health service at another site.

Under the proposed Stark II regulations, HCFA has interpreted the statutory requirement that a group practice distribute its income and overhead in accordance with "previously determined" methods to mean that a physician group must have an established method of distribution in place prior to the time period during which the group earns income or incurs costs (i.e., the group cannot arbitrarily decide how to make distributions at the time they are made). In addition, under the proposed rule, overhead expenses associated with and income from the practice must be distributed according to methods that demonstrate that the practice is a unified business (i.e., the methods must reflect "centralized decision making, a pooling of expenses and revenues, and a distribution system that is not based on each satellite office operating as if it were a separate enterprise" (*Preamble* at 1690)).

HCFA's interpretation of the Stark II group practice billing number requirement is substantially the same as its stance regarding the billing number requirement for in-office ancillary services (*see* discussion above).

Under the proposed regulations, a group practice member can be paid a share of the group's *overall profits*, as long as the physician's share is not calculated in a manner that is *directly* related to the volume or value of that physician's own referrals. For instance, a group practice would be able to pool its revenues and distribute equal shares to all of its members, even if such revenues were derived from referrals for designated health services. Alternatively, a group practice also might be able to distribute shares of overall profit according to a physician's ownership interest in the group, the number of hours a physician devotes to the group, or the difficulty of the physician's work in rendering patient care services. Of course, implementation of any profit sharing methodology still must be carefully structured to ensure the arrangement falls within one of the Stark II exceptions. Indeed, in the

About Vedder Price

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Health Care Services

preamble, HCFA cautions that "the narrower the pooling, the more likely it will be hat a physician will be deemed to be receiving compensation for his or her referrals." (*Preamble* at 1691.)

Personal Service Agreements

To fall under the exception for personal service arrangements, Stark II requires an arrangement to be set forth in writing. Recognizing that it would be illogical for all of a physician's services to be contained in a single agreement, HCFA has proposed to allow multiple agreements, provided that each agreement otherwise passes muster under Stark II and all separate agreements between the entity and the physician (or family members of the physician) incorporate each other by reference.

Leases for Items or Services

To qualify for one of the various lease exceptions, a physician or group must, among other things, set forth the arrangement in writing for a term of at least one (1) year. Under proposed Stark II regulations these written agreements also may contain a for-cause termination clause. If an agreement is terminated early for cause, however, the parties would not be able to enter into a new arrangement until after the expiration of the one (1) year period.

Physician Recruitment

The proposed rule allows hospitals to offer recruitment incentives to physicians relocating from a different geographical area. In order for this exception to apply, however, the regulations are clear that the recruited physician initially cannot reside in the hospital's geographical service area. Notwithstanding this requirement, in the preamble, HCFA suggests that recruitment payments made to a physician who resides within the hospital's geographical area alternatively might fall within the new compensation exception discussed below.

Reporting Requirements

Stark II requires each entity providing Medicare-covered services to provide carriers or intermediaries with certain information concerning the entity's ownership, investment,

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- Structuring of corporate networks, mergers, affiliations and acquisitions, including purchases and sales of practices and institutions;
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- Counseling in connection with implementation of strategic initiatives by health care entities, such as primary care satellite programs, physician recruitment and retention initiatives, and program development in emerging areas such as home health and outpatient mental health;
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Vedder, Price, Kaufman & Kammholz
A Partnership including Vedder, Price, Kaufman & Kammholz, P.C.

Chicago
222 North LaSalle Street
Chicago, Illinois 60601
312/609-7500
Facsimile: 312/609-5005

and compensation arrangements. If there are changes to this information, the regulations currently specify that an entity has a mere sixty (60) days from the date of any change to update its information. Recognizing that the sixty (60) day limit can impose a great burden on institutions (especially larger ones), the proposed regulations modify the reporting requirement to allow entities to annually report any changes that have occurred during the previous twelve (12) month period.

Newly Proposed Stark II Exceptions

The first newly proposed Stark II exception is for any compensation arrangement between a physician (or immediate family member), or any group of physicians (even if the group fails to qualify as a group practice) and an entity, provided the agreement meets the following criteria:

- Is in writing, signed by the parties, covering only identifiable items or services, all of which are specified in the agreement;
- Covers all the items and services to be provided by the physician or immediate family member to the entity, or alternatively, the agreement cross references any other agreements for items or services between any of the parties;
- Specifies a time frame which may be for any period of time (i.e., it may have a term of less than one year), although an agreement made for less than one year may be renewed any number of times if the terms of the agreement and the compensation for the same items or services do not change;
- Specifies and sets in advance the compensation that will be provided under the arrangement, which is consistent with fair market value and has not been determined in a manner that takes into account the volume or value of any referrals, payments for referrals for medical services that are not covered under Medicare or Medicaid, or other business generated by the parties;
- Involves a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties; and

New York
805 Third Avenue
New York, New York 10022
212/407-7700
Facsimile: 212/407-7799

New Jersey
354 Eisenhower Parkway
Plaza II
Livingston, New Jersey 07039
973/597-1100
Facsimile: 973/597-9607

- Meets a safe harbor under the Anti-Kickback Statute or otherwise be in compliance with the anti-kickback provisions in Section 1128B of the Social Security Act (42 U.S.C. § 1320a-7b).

The second newly proposed exception is for certain forms of "de minimis" compensation (e.g., free pharmaceutical samples, coffee mugs, etc.). Under this exception, noncash items or services (excluding cash equivalents such as stocks or bonds) would be exempt from Stark II's prohibitions. A $50 per-gift limit would apply to the exception, as would an annual aggregate limit of $300. Furthermore, the exception would only apply in situations in which the entity makes the compensation available to all similarly situated individuals, and the compensation could not be tied to the volume or value of physician referrals.

Practical Application

The proposed Stark II regulations are extremely comprehensive and resolve many inconsistencies that have beleaguered not only physicians but those charged with enforcing the law. If implemented, the regulations should instill more consistency in the way the government pursues Stark II violations. Although many issues still remain, the proposed regulations stand to offer much-need guidance in a very complex area of health care law.

If you desire more information about the proposed Stark II regulations or have a question concerning their application to a particular arrangement, please do not hesitate to call Michael E. Reed (312) 609-7428 or any other member of the firm's Health Care Group.

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