

CLE Resources: Texas Health Law Conference 1998

Stark Laws -- The Good, The Bad and the Ugly

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INTRODUCTION

On January 9, 1998, the Health Care Financing Administration published proposed regulations interpreting the expanded provisions of the federal self-referral law, known as the Stark Law, that went into effect January 1, 1995. 63 Fed. Reg. 1,659 (1998). Pursuant to the Stark Law, a physician may not refer Medicare or Medicaid patients to an entity for certain designated health services if the physician (or a family member) has a financial relationship with the entity, and the entity cannot bill for the services, unless the relationship qualifies for one of several exceptions specified in the law. As originally enacted effective January 1, 1992, the Stark Law referral and billing restrictions applied only to clinical laboratory services (commonly referred to as "Stark I").

Final regulations interpreting Stark I were published by HCFA on August 14, 1995 ("Stark I Rules"). These regulations made clear HCFA's position that the Stark Law is self-implementing (i.e., that publication of regulations is not required for enforcement of the law). The Stark Law referral and billing restrictions were expanded to several additional designated health services effective January 1, 1995 (commonly referred to as "Stark II"). For three years, physicians and health care entities have operated under a threat of enforcement without the benefit of published HCFA guidelines interpreting the many ambiguous provisions of the expanded law. The recently proposed regulations interpreting the Stark II restrictions ("Proposed Rules") answer some questions and raise others. This outline will discuss key issues identified in the Proposed Rules.

A. DEFINITIONS

The definitions contained in the Stark Law are integral in determining the scope of arrangements subject to the law. Thus, a considerable portion of the preamble language to the Proposed Rules is devoted to a discussion of applicable definitions.

1. *Designated Health Services.* The Proposed Rules furnish significant guidance in ascertaining the "designated health services" set forth in the Stark Law. HCFA has chosen, in general, to base the definitions for designated health services on existing definitions in the Medicare program, deviating only when appropriate to fulfill the purpose of the law.
2. *Clinical laboratory services.* The definition of clinical laboratory services remains unchanged from that established in the Stark I Rules.
3. *Physical therapy services.* Physical therapy services is defined to include speech-language pathology services, as well as physical therapy services that are covered under Medicare, regardless of where they are furnished and by whom, or how they are billed. Thus, the definition includes outpatient physical therapy and speech-language pathology services, diagnostic or therapeutic physical therapy and speech-language pathology services furnished to an inpatient of a hospital or skilled nursing facility ("SNF"), and physical therapy and speech-language pathology services furnished as "incident to" a physician's services.
4. *Occupational therapy services.* As with the definition of physical therapy services, HCFA interprets the definition of occupational therapy services broadly, including any occupational therapy services that are covered under Medicare, regardless of where they are furnished and by whom, or how they are billed.
5. *Radiology services, including magnetic resonance imaging, computerized axial tomography scans, ultrasound services, and radiation therapy services and supplies.* Radiology services and radiation therapy and supplies is defined to include any diagnostic test or therapeutic procedure using X-rays, ultrasound or other imaging services, computerized axial tomography, magnetic resonance imaging, radiation or nuclear medicine, and diagnostic mammography services, as covered under the Medicare program. In a surprising move, HCFA proposes to include the professional component of these services. This proposal will affect permissible compensation methods for physicians, as discussed later in this

article. The preamble explains that whenever a technological radiology service is overutilized, it follows that a physician's radiology service also will be overutilized.

On the other hand, certain radiographic procedures which could qualify as radiology services are not included in the definition. Screening mammography is specifically excluded. In addition, the proposed definition specifically excludes "any invasive radiology procedure in which the imaging modality is used to guide a needle, probe, or a catheter accurately." This exclusion is based on the theory that the radiology services in these procedures are merely secondary to another procedure ordered by the physician. HCFA states that the secondary procedures are not subject to abuse in the same way that the primary procedures often are. Examples of invasive radiology procedures set forth in the preamble include percutaneous transluminal angioplasty, biopsies, and myelograms.

6. *Durable medical equipment and supplies.* The Proposed Rules incorporate the definition of durable medical equipment ("DME") found in the Social Security Act (i.e., equipment such as iron lungs, oxygen tents, hospital beds, and wheelchairs used in a patient's home, whether furnished on a rental basis or purchased). Supplies necessary for the effective use of the DME are included in this designated health service. For example, if an infusion pump is covered as DME, the drugs and biologicals that are put directly into the pump would be included as supplies. Because the number of items considered to be DME is quite extensive, HCFA has declined to identify each of them in the Proposed Rules. The preamble, however, does set forth a list of 32 general categories of DME. The preamble also clarifies that home dialysis supplies, equipment, and self-care home dialysis support services provided to individuals with ESRD are not considered DME and, thus, do not constitute a designated health service. Finally, the preamble notes that the Stark Law provides an exception for in-office ancillary services other than DME, excluding infusion pumps. Although the statutory language would appear to exempt infusion pumps from the prohibition on a physician referring DME, HCFA notes that the exception applies only to in-office services and would not apply to infusion pumps that are only picked up at a physician's office to be used at home, or that are delivered to a patient's home.

7. *Parenteral and enteral nutrients, equipment and supplies.* The Proposed Rules define parenteral and enteral nutrients, equipment, and supplies as items and supplies needed to provide nutrition to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of specific nutrients to maintain strength commensurate with his or her general condition.

8. *Prosthetics, orthotics, and prosthetic devices.* This designated health service comprises three related components. The Proposed Rules define "prosthetics" as artificial legs, arms, and eyes, and "orthotics" as leg, arm, back, and neck braces. Finally, the Proposed Rules define "prosthetic device" as a device that replaces all or part of an internal body organ, including colostomy bags, one pair of conventional eyeglasses or contact lenses furnished subsequent to cataract surgery with insertion of an intraocular lens, cochlear implants, cardiac pacemakers, and incontinence control devices. Intraocular lenses are also included in the definition of prosthetic devices, although HCFA points out that lenses implanted in an ambulatory surgery center ("ASC") are included in the ASC payment rate and thus protected by the Stark Law exception for ASC services. This designated health service also specifically includes the supplies associated with such prosthetic devices. Diabetic shoes, casts, and splints are not included as prosthetics, orthotics, or prosthetic devices.

Although requested to do so, HCFA declined to specifically exclude any device that is implanted by a physician as part of a surgical procedure. Recognizing that physicians are not likely to subject patients to surgical procedures in order to boost profits on an implantable device, HCFA highlights several financial arrangements that might influence a physician to select a prosthetic device based on financial incentives rather than on the best interest of the patient. For example, the preamble states that a physician may receive compensation from a manufacturer or supplier of a device in exchange for the physician's agreement to use the company's device exclusively. HCFA is soliciting comments specifically on this issue.

9. *Home health services.* The Proposed Rules clarify areas of inconsistency and confusion in the area of home health services. In defining "home health services" the Proposed Rules refer to the statutory and regulatory definitions, which provide that home health services are items and services furnished to an individual who is confined to the home under the care of a physician, and in need of at least one of the following services: intermittent skilled nursing services, physical therapy services, speech-language pathology services, or continuing occupational therapy services. The preamble text is also very clear that home health services can only be provided by a home health agency ("HHA"). As a result of this strict definition, the home health services furnished by a hospital-based HHA cannot qualify under the

ownership exception for designated health services rendered by the hospital. The preamble states: "even if a hospital owns an HHA, the Stark Law exception for hospital ownership which applies to designated health services 'provided by a hospital,' would not apply to home health services provided by a hospital-based HHA."

The Proposed Rules also clear up an inconsistency between the Stark Law and the Medicare home health regulation regarding certification requirements. It is a positive change for providers. The certification regulation prohibits physicians from certifying a plan of care for home health services if the physician has an indirect or direct financial or contractual arrangement with an HHA worth more than \$25,000 or five percent of the agency's total operating expenses, or an ownership interest in an HHA in excess of five percent. The problem existed because a physician receiving fair market value compensation (not taking into account volume or value of referrals) could qualify for an exception under the Stark Law (e.g., the employment or personal services exception), but could still be in violation of the certification regulation if his or her compensation were greater than \$25,000 or five percent of the HHA's total operating expenses. With respect to ownership interests, the Stark Law includes any level of ownership as a financial relationship subject to the referral restrictions; thus, a physician could hold an ownership interest that would subject him or her to the Stark Law, but not the certification regulation. The Proposed Rules eliminate the thresholds and exceptions found in the certification regulation, replacing them with the Stark Law definition of "financial relationship" and the Stark Law exceptions.

10. *Outpatient prescription drugs.* The preamble notes that the Medicare program does not cover a category of services called "outpatient prescription drugs." The Proposed Rules define the term "outpatient prescription drugs" to include only those drugs covered under the Medicare Part B benefit that require a prescription (even if routinely furnished in a physician's office without one). The definition also includes biologicals (i.e., a drug product derived from a living organism or its products, such as serums, vaccines, antigens, and antitoxins) covered under Part B. Erythropoietin ("EPO") and several other drugs furnished as a part of dialysis treatment for ESRD patients who receive dialysis treatment at home or in a facility, however, are explicitly excluded.

11. *Inpatient hospital services.* The Proposed Rules include in the definition of "inpatient hospital services" the following services when furnished to an inpatient of a participating hospital:

- Bed and board;
- Nursing services;
- Use of hospital facilities;
- Medical social services;
- Drugs, biologicals, supplies, appliances, and equipment;
- Certain diagnostic and therapeutic services; and
- Medical or surgical services provided by interns and residents.

Inpatient services furnished by a psychiatric hospital or a participating rural primary care hospital ("RPCH") are included in the definition. Inpatient hospital services includes services furnished directly by the hospital, as well as by others under arrangements with the hospital. Although asked to do so, HCFA specifically declined to exclude services involving lithotripters that use extracorporeal shock wave lithotripsy ("ESWL") from the definition of inpatient hospital services. Although HCFA acknowledged that overutilization would be unlikely in the area of ESWL (used in painful kidney stone situations), the preamble noted that the agency considers arrangements involving ESWL equipment and physicians as a potential area of patient abuse because of the financial incentives involved. The preamble specifically solicited comments on the inclusion of ESWL services in the definition of "inpatient hospital services."

Not included in the definition of "inpatient hospital services" are:

- Services of physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified nurse anesthetists and qualified psychologists who bill independently;
- Skilled nursing facility-type care furnished by a hospital that has a swing-bed approval or any nursing-facility type care furnished as a Medicaid service; and
- Dialysis services furnished by a hospital that is not certified to provide ESRD dialysis services.

HCFA excludes these dialysis services because they are provided only in emergency situations or when the primary reason for the hospital admission is not maintenance dialysis; thus the risk of program abuse is believed to be low.

12. *Outpatient hospital services.* HCFA has proposed to define "outpatient hospital services" as therapeutic outpatient hospital services furnished "incident to" a physician's service, diagnostic outpatient hospital services, and partial hospitalization services; outpatient services furnished by a psychiatric hospital; outpatient rural primary care hospital services; and services involving lithotripters using ESWL. HCFA states, "we would consider all covered services (either diagnostic or therapeutic) performed on hospital outpatients that are billed by the hospital to Medicare (including arranged for services) as outpatient hospital services."

B. Direct Supervision

The definition of direct supervision is relevant for qualification for the in-office ancillary services exception, which requires that services be personally furnished by a physician, or by individuals who are directly supervised by a physician.

1. *Physical presence.* The Proposed Rules clarify the definition of direct supervision set forth in the Stark I Rules, which provided that direct supervision means supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time that services are being performed, by specifying that the physician must be present in the same suite in which the services are being furnished. This is relevant for group practices with multiple office suites within the same building.

2. *"Limited absence."* The Proposed Rules also alter slightly the definition of direct supervision to allow the supervising physician very limited absences from the office suite. Recognizing the impracticality of requiring a physician to be on the premises the entire time a designated health service is being furnished, HCFA's Proposed Rules still consider the physician present during routine absences for short periods (such as a lunch break) or brief unexpected absences (e.g., medical emergencies in a hospital), as long as the absences occur during time periods in which the physician is otherwise scheduled and ordinarily expected to be present, and the absences do not conflict with any other requirements in the Medicare program for a particular level of physician supervision. Thus, if Medicare coverage requirements set a less stringent supervision level for a particular designated health service (such as general supervision for certain x-rays), compliance with the in-office ancillary services exception will nonetheless require that the service be directly supervised. If Medicare coverage requirements set a more stringent supervision level (such as personal supervision for cardiovascular stress testing), the in-office ancillary services exception may be used for such designated health services only if the more stringent personal supervision requirement is met. The question of whether an absence qualifies as a limited absence will be addressed on a local carrier level, based on individual circumstances. Similarly, local carriers are granted the authority to address the issue of what configuration of rooms constitutes a suite (e.g., whether multi-floor offices in a single building can qualify as one suite).

C. Entity

1. *Definition.* The definition of an "entity" under the Proposed Rules is extremely broad. An "entity" means "a physician's solo practice or a practice of multiple physicians that provides for the furnishing of designated health services, or any other sole proprietorship, trust, corporation, partnership, foundation, not-for-profit corporation, or unincorporated association." The tremendous breadth of this definition reflects HCFA's interpretation that the Stark Law encompasses *any* entity that provides designated health services, without qualifications or limits. Additionally, HCFA clarifies that it regards an individual physician or group of physicians as an "entity" when they refer patients to themselves, or among themselves. This, according to HCFA, is because the statutory definition is not limited to referrals by a physician to an outside or unrelated entity. Additionally, there would be no need for the physician services exception or the in-office ancillary services exception in the Stark Law if referrals inside a solo practice or group practice were not covered by the definition of "entity."

2. *Characteristics.* In the preamble to the Proposed Rules, HCFA also clarifies the characteristics of an entity that provides for the furnishing of designated health services. For example, an "entity" does not include a person or business that owns the "components of the operation" without owning the operation itself. For instance, a provider that owns the building that houses an entity providing for the furnishing of designated health services, or the equipment used by the entity, is not an "entity" for purposes of the Stark Law. In other words, the "entity" must be the organization furnishing or providing the designated health service, and billing for the service, or receiving payment for the service from the billing entity as part of an under arrangement or similar agreement.

3. *When is an entity involved in the furnishing, or providing for the furnishing of, designated health services?* HCFA also attempted to provide guidance regarding this common question. According to HCFA, the Stark Law prohibitions apply to physician referrals to any entity that directly furnishes designated health services to Medicare and Medicaid patients, as well as any entity that arranges "for the furnishing of" these services by contracting with other providers, when the arranging entity is the entity that bills for the services. Again, HCFA cites a Stark Law exemption as justification for its interpretation; i.e., services are excepted if they are furnished by an organization that functions under a prepaid plan, such as an HMO. In the HMO situation, the HMO contracts with a broad range of independent providers to provide health service to enrollees, and the Stark Law exception makes no distinction between the services provided directly by the HMO and those that are arranged by the HMO and furnished under contract by outside providers.

D. Financial Relationship

1. *What it means to have a financial relationship.* The Proposed Rules clarify that a referral alone is not a financial relationship. A financial relationship consists of an ownership or investment interest in the entity or a compensation relationship with the entity.

The Proposed Rules clarify many issues arising with respect to interests that constitute ownership interest for Stark Law purposes. The Stark Law provides that an ownership interest can be through equity, debt, or other means. The Proposed Rules clarify that "ownership through equity" refers to a direct ownership interest that does not involve debt (e.g., stock held in an entity or an investment (such as a capital contribution) in a partnership). A physician or family member holds an ownership interest in an entity "through debt" any time the physician or family member has lent money or given other valuable consideration to the entity, and the debt is secured (in whole or in part) by the entity or by the entity's assets or property. HCFA states that an unsecured or nonconvertible loan to an entity does not constitute an ownership interest, although such a loan would likely qualify as a compensation arrangement. Finally, the Proposed Rules provide that ownership through debt is not established when a physician or family member has received a loan *from* an entity. Such a loan would, however, constitute a compensation arrangement, necessitating qualification for an exception.

With respect to ownership through other means, the Proposed Rules state that options in nonvested interests (e.g., nonvested stock options or retirement funds) are partial ownership interests that qualify as ownership for purposes of the Stark Law. HCFA reasons that whether the interest is a present or future interest, the physician has the same incentive to refer to the entity in which it holds such interest. A financial relationship can involve more than the Medicare or Medicaid programs. The Proposed Rules emphasize that a financial relationship can exist between a physician and an entity even if that relationship does not involve designated health services or the Medicare or Medicaid programs. The Proposed Rules give as examples payments to a physician for non-medical types of items or services, or for housing or travel expenses.

2. *Indirect financial relationship.* Financial relationships giving rise to the Stark Law restrictions may be direct or indirect. The Proposed Rules clarify that the concept of "ownership" includes an interest that is at least one level removed from direct ownership. In fact, the Proposed Rules interpret indirect ownership to mean an interest that can be removed by an unlimited number of levels. For example, when a physician (or a family member) has an interest in an entity that has an interest in another entity that in turn holds the ownership interest in the entity that provides designated health services, this would constitute an indirect ownership by the physician or family member.

In the Stark I Rules, a "compensation arrangement" was defined as any arrangement involving any remuneration, direct or indirect, between a physician (or a physician's family member) and an entity. HCFA believes that a physician or family member can receive compensation from an entity even if the payment is "funneled through" a business or other entity or association and even if the payment changes form before the physician actually receives it. The Proposed Rules provide as an example the situation where a hospital pays a group practice for physician services under a personal services arrangement and the group practice pays physician members a salary that in some way reflects the hospital's payments. This scenario represents an indirect compensation arrangement between the hospital and the physician members. In the absence of an exception, the physicians would be prohibited from referring to the hospital for the furnishing of designated health services. Fortunately, HCFA would allow the Stark Law exceptions to apply in an indirect manner. Thus, where the hospital pays a group practice under a personal services arrangement, the physicians could make referrals to the hospital if the arrangement

with the hospital meets the criteria under the personal services exception. The Proposed Rules solicit comments on HCFA's approach to defining indirect compensation.

E. Group Practice

1. *Definition.* In order to qualify for the in-office ancillary services exception, which allows physicians to provide and bill for designated health services to their patients, a physician group must meet the definition of group practice set forth in the Stark Law. Qualification as a group practice is also relevant for other exceptions. Thus, a significant portion of the preamble is devoted to a discussion of group practice issues.

The Stark Law defines a group practice as "two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association." The preamble to the Proposed Rules clarifies that a group practice must be a single legal entity, and that individual physicians merely holding themselves out as a group will not qualify as a group practice. Two or more groups of physicians, each organized as separate legal entities also will not qualify as a group practice, except that physician owners of a group may be individually incorporated (e.g., as a professional association or corporation).

2. *Requirements.* In addition to requirements relating to the legal form of a group practice, a group of physicians is a group practice only if the following requirements are met:

a. Each physician member of the group furnishes substantially the full range of services that the physician routinely furnishes, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel.

- The Stark I Rules limited the services applicable to determining compliance with this requirement to patient care services that address the medical needs of specific patients. HCFA now defines the full range of services that a physician routinely furnishes to include both services that address the medical needs of patients and services that benefit the group practice. Therefore, management, training, and other administrative services that benefit the group may be counted as part of the full range of services that a physician member routinely provides.

b. Substantially all of the services of the physician members of the group are furnished through the group, billed under a billing number assigned to the group, and the amounts so received are treated as receipts of the group.

- HCFA proposes to continue to follow the standard established in the Stark I Rules that "substantially all" of the services provided by physician members requires that at least 75 percent of the physician members' total patient care services, in the aggregate, are furnished through the group. Like the scope of patient care services that may be included in the "full range of services" requirement discussed above, HCFA proposes to expand the scope of patient care services that may be counted towards fulfilling the 75 percent requirement. The Proposed Rules allow member physicians to include both services that address the medical needs of patients and services that benefit the group to establish that the member physicians provide at least 75 percent of their total patient care services through the group. However, nonpatient care services, such as teaching in a medical school or doing outside research, are not included.
- HCFA continues to believe that determining the amount of patient care services rendered through the group should be a measure of the amount of time a physician member spends providing patient care services. Although other measurement methods (e.g., a physician's personal income, number of patient encounters, number of Relative Value Units) were considered in response to industry requests, HCFA rejected these in favor of patient care time, due to difficulties associated with the various alternative measures. The Proposed Rules specify that detailed time records would not be required to verify a group's calculation and that a group can assume that physician members work a 40-hour week, unless the group can show evidence of a longer or shorter work week. The Proposed Rules solicit comments concerning further methods of determining patient care services.
- With respect to the billing requirements, HCFA acknowledges that groups may have more than one provider number and may bill under any of its assigned numbers.

c. The overhead expenses of and the income from the practice are distributed in accordance with methods previously determined.

- HCFA proposes to interpret this requirement to mean that the methods of distribution must be in place prior to the time period the group has earned the income or incurred the costs. Moreover, 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 or specialty operating as if it were a separate enterprise.

d. No physician member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician except that a group practice member may be paid a portion of the group's overall profits, or a productivity bonus based on services personally performed or services incident to personally performed services, so long as the share or bonus is not determined in any manner directly related to the volume or value of referrals by the physician.

- This requirement was added in the Stark II legislation, effective January 1, 1995, and has generated significant comment in the industry. The Proposed Rules state that the volume or value standard precludes a group practice from paying physician members for each referral they personally make or based on the value of referred services. In a rather surprising move, HCFA proposes to limit referrals for purposes of the volume or value standard to the request by a physician for, or the establishment of a plan of care that includes, a designated health service covered under Medicare. Thus, the preamble specifies that a group practice member can receive compensation based on the volume or value of referrals for non-Medicare and Medicaid patients. Moreover, a group practice could potentially compensate members on the basis of referrals for Medicare or Medicaid services that do not constitute designated health services, although the preamble cautions that this methodology could raise potential illegal remuneration issues. Since self-referrals are also referrals under the Stark Law, the Proposed Rules caution against the payment of profits or productivity bonuses on the basis of revenue generated from designated health services furnished to Medicare patients even when the physician personally furnishes the service unless the service was requested by another physician. This conclusion is particularly relevant now that the definition of radiology and radiation therapy services includes the professional component. As a result, group practice members cannot receive compensation directly based on radiology interpretations furnished by the physician for his or her own patients.

e. Members of the group personally conduct at least 75 percent of the physician patient encounters of the group practice.

- First, the preamble specifies that an encounter constitutes any appointment during which a group practice patient is seen by a physician. The Proposed Rules also amend the definition of group practice member. The Stark I Rules broadly defined a member of a group practice to include physician partners and full-time and part-time physician contractors and employees. HCFA now proposes to include all physician owners (not just partners) and to eliminate independent contractor physicians from the definition of group practice member. HCFA's rationale in eliminating independent contractor physicians was to facilitate the ability of group practices that contract with large numbers of physicians to perform specialty and other services on a part-time or sporadic basis to comply with the requirement that substantially all (75 percent) of the services of the group practice members be furnished through the group. However, removing independent contractors from the definition of group practice members may make it more difficult for some groups to meet the group practice requirement that group members conduct at least 75 percent of the physician-patient encounters of the group. It further prohibits independent contractors from supervising the provision of designated health services on behalf of the group under the "in-office ancillary services" exception. It is important to note that the removal of independent contractor physicians from the definition of group practice member does not mean that independent contractors are prohibited from making designated health service referrals to the group. Although the in-office ancillary services exception would no longer be applicable to referrals to the group by independent contractor physicians, the referrals may be allowed if the compensation relationship between the independent contractor physician and the group practice complies with one of the Stark Law compensation exceptions.

f. The conditions contained in the group practice definition apply only with respect to the services furnished within the faculty practice plan in the case of a faculty practice plan associated with a hospital, institution of higher education, or medical school with an approved medical residency training program in

which physician members may furnish a variety of different specialty services and furnish professional services both within and outside the group, as well as perform other tasks such as research.

3. *Additional issues.* The Proposed Rules also clarify additional issues relevant to group practices. For example, HCFA rescinds its position that a group practice member's financial relationship with a provider, if not excepted from the Stark Law, results in application of the referral ban to all members of the group practice. HCFA states that the statute was drafted to cover the referral behavior of individual physicians and to regulate the entities to which they refer. Therefore, it now takes the position that preclusion of one member of a group practice from referring to a particular entity that furnishes designated health services should not "taint" the referrals of the entire group. HCFA specifically states: "There does not appear to us to be any clear reason to extend the effects of one physician's relationships and behaviors to other physicians, just because they are all members of the same group practice." HCFA states, however, that if a group member is in a position to exert influence or control over the referrals of the other group physicians, the prohibition could still apply.

F. Referral

1. *Concept of a "referral."* HCFA believes that the concept of a "referral" is a broad one. The Stark Law specifies that referrals include:

a. The request by a physician for an item or service for which payment may be made under Medicare Part B, including the request for a consultation with another physician and tests or procedures performed in conjunction with the consultation; and

b. The establishment of a plan of care by a physician that includes a designated health service.

The Proposed Rules interpret Aitems or services for which payment may be made under Part B" and Aplans of care including designated health services" to mean items or services that ordinarily "may be" covered under Medicare for a Medicare eligible individual, regardless of whether Medicare would actually pay for this particular service, at the time, for the particular individual. The Proposed Rules provide, as an example, the situation where Medicare would not pay for a service because the beneficiary has not met the applicable deductible, specifying that referrals for the service would still be subject to the restrictions. The Proposed Rules clarify that a request occurs after a physician has initially examined a patient or furnished physician's services that are not designated health services, and the physician asks for a service in any way or indicates that he or she believes the service is necessary, whether verbally or in writing. The Proposed Rules also state that a consultation occurs whenever a physician requests that a patient see another physician, such as a particular specialist, but the original physician retains control over the care of the patient, including any care related to the condition that prompted the consultation. In other words, HCFA would consider it a consultation if the original physician gathers information from the consultant physician about his or her examination of the patient and any test results, and then makes a decision about how to proceed with the patient's care.

The Proposed Rules state that the concept of a referral under the Stark Law is limited to referrals for designated health services. The concept of "referral" also covers situations in which physicians refer to themselves or among themselves. HCFA believes that a physician has made a referral when he or she requests a designated health service covered under Part A or Part B or establishes a plan of care that includes a designated health service even if the physician furnishes the service personally.

2. *Exclusions.* The Stark Law excludes from the definition of a "referral" a request by:

a. A pathologist for clinical diagnostic laboratory tests and pathological examination services,

b. Radiologist for diagnostic radiology services, and

c. A radiation oncologist for radiation therapy, if the services are furnished by (or under the supervision of) the pathologist, radiologist, or radiation oncologist as the result of a consultation requested by another physician.

The Proposed Rules state that the level of supervision required if another individual, such as a technician, actually furnishes the services is "the level of supervision ordinarily required under Medicare coverage and payment rules or, when they apply, the health and safety standards, for the particular services at issue in the particular locations in which the services will be furnished."

3. *Additional issues.* The preamble to the Proposed Rules addresses additional issues related to prohibited referrals. For example, when a physician requests a designated health service but someone other than the physician refers the patient to a specific provider (e.g., the discharge planner at a hospital), HCFA proposes to "impute" the physician's referral to the other person when the physician has the ability to control or influence the individuals who select the actual provider or where the physician is in a position

to be compensated for the referrals by those who can control or influence the actions of the person who actually selects the provider. Thus, a physician employee of a hospital who refers a patient to the hospital's discharge planner for laboratory tests, who then refers the tests to the hospital's laboratory, has made a referral to the hospital C an entity providing designated health services with which the physician has a financial relationship.

Where a physician requests a designated health service without establishing a record of whether the patient was referred to a specific provider, HCFA proposes to presume that the service resulted from the physician's referral to the provider furnishing the service if the provider is one with which the physician, or a family member, has a financial relationship. HCFA proposes to permit physicians to rebut this presumption by establishing that they mentioned no specific provider or supplier, or that the patient was directly referred by some other independent individual or through an unrelated entity.

G. Remuneration

1. *Definition.* A compensation arrangement subject to the Stark Law includes any arrangement involving remuneration between a physician (or immediate family member) and an entity. The Stark Law defines remuneration as any remuneration made directly or indirectly, overtly or covertly, in cash or in kind. The Proposed Rules state that remuneration generally involves any payment of cash, property, or services whether or not either or both parties receive a net benefit. For example, HCFA regards as remuneration the repayment of a loan, even if there are no accompanying interest payments. HCFA further states that the statute is designed to prohibit referrals whenever a physician makes a payment to an entity or an entity makes a payment to a physician, regardless of who profits or gains. The statute contains a presumption that if there has been a payment of any kind, a physician should not refer.

2. *Exclusions.* Certain kinds of remuneration are specifically excluded from the definition of remuneration, including forgiveness of amounts owed for inaccurate tests or mistakenly performed tests, the correction of minor billing errors, and the provision of items, devices, or supplies that are used *solely* to collect, transport, process, or store specimens for the entity providing the item, device, or supply. The Proposed Rules note that items or devices furnished by an entity qualify for this exclusion only if they are used solely for the entity that supplied them, and that the number or amount of these items should be consistent with the number or amount that is used for specimens that are actually sent to the entity for processing.

3. *Additional issues.* More informative than what is excluded from the definition of remuneration is HCFA's discussion of what is included. The Stark I Rules included discounts in the definition of remuneration. The Stark Law provides an exception for payments made by a physician to an entity as compensation for items or services (other than clinical laboratory services), if the items or services are furnished at fair market value. Therefore, any amounts that a physician pays for items or services that do not reflect fair market value, such as certain discounted items or services, would not meet the exception. The Proposed Rules dispel the notion that HCFA considers all discounts to fail the fair market value exception by stating the following fair market value standard for discounts:

- a. The discount is offered pursuant to an arm's length transaction;
- b. The entity offers the discount to all similarly situated individuals regardless of whether they make referrals to the entity;
- c. The discount does not reflect the volume or value of any referrals the physician has made or will make to the entity; and
- d. The discount is passed on to Medicare or other payers. HCFA provides as an example of a discount that would fail the standard, situations where physicians purchase oncology drugs from a manufacturer and mark the drugs up when billing Medicare.

The Proposed Rules also create a new exception that would allow physicians to receive a discount based on the volume of their referrals to an entity, if the discount is passed on in full to the patients or their insurers (including Medicare), and does not inure to the benefit of the physician in any way.

STARK LAW EXCEPTIONS

A. Exceptions that Apply to Ownership or Investment Interests and to Compensation Arrangements

1. *Exception for physician services.* There is no prohibited referral when physician services are performed personally by, or under the personal supervision of, another physician in the same group practice as the

referring physician. HCFA clarifies that the exception for physician services only applies to services performed by a physician (such as surgery, consultation, and home, office, and institution visits) and does not include services provided by nonphysicians as "incident to" or ancillary services. The exception applies to physician services constituting designated health services, such as professional radiology interpretations. The Proposed Rules state that the physician performing the services must either be a member of the same group practice as the referring physician, or may be a nonmember physician who is performing physician services under the personal supervision of a group practice physician member. Personal supervision would mean that the group practice physician is legally responsible for monitoring the results of the service and available to assist the nonmember physician, although the group practice physician is not required to be present when the service is performed. Under this exception, independent contractor physicians who are no longer considered "members" of the group by virtue of the Proposed Rules, could still provide physician services and fit within this exception, provided that a group member personally supervises the nonmember physician.

2. *In-office ancillary services exception.* Once a physician group establishes that it is indeed a group practice, the group members may make referrals for designated health services within the group as long as the referrals fall within the in-office ancillary services exception. Similarly, a solo practitioner can provide designated health services only if the exception is met. The in-office ancillary services exception applies to all designated health services other than parenteral and enteral nutrients and DME, with the exception of infusion pumps. The Proposed Rules do, however, specify that a physician may provide crutches to a Medicare or Medicaid patient as long as the physician realizes no direct or indirect profit from the crutches (i.e., the physician bills the crutches at cost). The Proposed Rules make several changes to conform the regulation to the statutory changes made by the Stark II legislation.

a. *Who may furnish services.* The in-office ancillary services exception requires that the services be furnished by:

- The referring physician,
- A physician who is a member of the same group practice as the referring physician, or
- Individuals who are directly supervised by the referring physician or by another physician in the same group practice as the referring physician. As discussed in more detail above, the direct supervision requirement mandates that a physician be present in the same suite as the individual providing the service during the time the service is furnished.

b. *Location.* The in-office ancillary services exception applies only when the ancillary services are performed in certain locations:

- In the same building in which the referring physician (or another physician who is a member of the same group practice) furnishes physician services unrelated to the furnishing of designated health services;
- In a building that is used by a group practice for the centralized provision of some or all of the group's clinical laboratory services; or
- In a building that is used by a group practice for the centralized provision of the group's designated health services (other than clinical laboratory services).

c. *"Same building."* The Proposed Rules clarify that the "same building" requirement means the same physical structure, with one address, and not multiple structures connected by tunnels or walkways. Further, HCFA believes that a mobile X-ray van that pulls into the garage of a building is not part of that building.

d. *Centralized location.* To qualify for the in-office ancillary services exception by using a centralized location for the provision of designated health services, HCFA states that the location is centralized if it services *more than one* of a group's offices, and if it furnishes one or more designated health services. This language implies that a group practice with only one office may not have a separate building in which it furnishes its designated health services but must perform its designated health services in the same building in which it performs all other services. HCFA does confirm, however, that a group practice with multiple locations may have more than one centralized location for the provision of designated health services. In each such centralized location, the group practice would be required to have a physician member present to either perform or directly supervise the performance of the designated health services.

e. *Who may bill.* Finally, the in-office ancillary services exception imposes limitations with respect to who may bill for such services. The in-office ancillary service must be billed by:

- The physician performing or supervising the services,
- A group practice of which the physician is a member, or
- An entity that is wholly-owned by the physician or group practice.

The Proposed Rules amend these requirements by adding, in the case of billing by the physician member's group practice in (b) above, that the service must be billed under a number assigned to the group. A group may, however, have multiple assigned billing numbers. For services billed by an entity wholly-owned by the physician or group, the service need not be billed in the group's name if the wholly-owned entity may bill under its own provider number.

3. *Exception for services provided under prepaid health plans.* The preamble to the Proposed Rules recites HCFA's intent to interpret the prepaid plan exception to the Stark Law in a manner that safeguards the Medicare and Medicaid programs from abuse, while facilitating the evolution of integrated delivery and other health care delivery systems. The prepaid plan exception applies to services furnished to enrollees by a health maintenance organization or a competitive medical plan that has contracted with Medicare, an organization functioning under a demonstration project, or a federally qualified HMO. In the preamble to the Proposed Rules, HCFA interprets this "prepaid plan" exception broadly to cover not only services furnished by the aforementioned organizations themselves, but also those services furnished to the organization's enrollees by outside physicians, providers, or suppliers under contracts with these organizations, or persons or entities with whom the outside physicians, providers, or suppliers have contracted. HCFA also proposes a new section to extend the prepaid exception to services provided by the categories of Medicaid-contracting managed care plans analogous to the managed care entities that provide services to Medicare enrollees. Although requested to do so, HCFA declined to extend the prepaid plan exception to hybrid organizations and systems, such as preferred provider organizations. The Proposed Rules state these "hybrid" structures will continue to have to meet another exception (e.g., the personal services exception or the proposed general exception for fair market value compensation) to avoid violation of the referral prohibition.

A physician who furnishes services to managed care patients under a personal services contract and refers fee-for-service Medicare patients for designated health services to a physician, provider, or supplier that is "affiliated" with the managed care entity but not "part of it," would not be referring to the managed care entity. By contrast, a physician who furnishes services to enrollees of a federally qualified HMO could not refer fee-for-service Medicare patients to the HMO's laboratory without satisfying one of the Stark Law compensation-related exceptions. HCFA acknowledges that some providers contracting under managed fee-for-service programs (e.g., Medicaid primary case management programs) may not be eligible for any of the existing exceptions at law or Proposed Rules and, therefore, solicits comments from states on the potential impact of the referral prohibition on these programs and the providers who contract under them.

B. Exceptions That Apply Only to Ownership or Investment Interests

1. *Securities.* The Stark Law exception for ownership of publicly traded securities states that a physician's ownership of investment securities "which may be purchased on terms generally available to the public" may not be considered an ownership interest if certain conditions are met. The Proposed Rules interpret the "may be purchased" language to mean that, at the time the physician or immediate family member purchased or acquired the securities, the securities could be purchased on the open market, even if the physician or family member did not acquire them on such terms. Thus, if a physician inherits securities or acquires them without actually purchasing them on the open market, this acquisition could fit within the exception.
2. *Hospital ownership.* The Stark Law contains an exception for ownership interests held by physicians in a hospital if the referring physician-owner is authorized to perform services at that hospital, and the physician has an ownership or investment in the hospital as a whole and not merely in a department or subdivision of the hospital. HCFA interprets this exception as applying to designated health services that are furnished by the hospital only, and states that this exception does not cover services furnished by any other provider or entity owned by the hospital, such as a hospital-owned home health agency or skilled nursing facility. Therefore, if a physician is on the medical staff at a hospital and has an ownership interest in the whole hospital, that physician may refer patients to the

hospital for designated health services. However, the same physician may not refer patients to a hospital-owned home health agency without meeting another exception.

The Proposed Rules confirm that the hospital ownership exception also may apply if a physician has an ownership interest in a network or health system that owns a hospital, if the physician is authorized to perform services at the chain hospital to which the physician wishes to refer. This last requirement is not met if the physician merely has these privileges with other hospitals in the chain, but not in the hospital to which the physician wishes to refer. In other words, a physician with an ownership interest in a health system may refer patients for designated health services to a hospital within that system, provided that the physician is authorized to admit patients to that chain hospital.

C. Exceptions That Apply Only to Compensation Arrangements

1. *Clarification of general requirements.* The majority of compensation-related exceptions in the Stark Law require that compensation be consistent with fair market value, not be determined in a manner that takes into account the volume or value of referrals, and be commercially reasonable.

The Proposed Rules clarify these aspects of the compensation-related exceptions.

a. *Fair market value.* The first requirement common to the Stark Law exceptions is that the compensation be consistent with fair market value. The Proposed Rules incorporate the definition of fair market value from the Stark I Rules; i.e., the value in arm's-length transactions, consistent with general market value, and add as a definition of general market value, the price that an asset would bring or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties on the date of acquisition of the asset or at the time of execution of the service agreement. This usually means the price paid in a bona fide sale of a similar asset in a particular market or the compensation included in a service agreement containing similar terms. The specific requirements regarding rentals and leases (e.g., that the value not include considerations of proximity) are retained.

b. *Volume or value of referrals.* Most compensation-related exceptions include a provision prohibiting compensation on the basis of the volume or value of referrals. Some exceptions provide that compensation cannot be based on the volume or value of referrals or any other business generated between the parties. The Proposed Rules interpret this additional language of "other business generated between the parties" as clarification of the volume or value concept. Accordingly, the "volume or value" standard represents a standard that includes other business that is generated between the parties. The Proposed Rules also disclaim any difference between exceptions which simply preclude compensation that takes into account the volume or value of referrals, and those which prohibit taking into account, *directly or indirectly*, the volume or value of referrals. Finally, the Proposed Rules provide that the volume or value standard only applies to referrals of Medicare or Medicaid patients for designated health services.

In response to a question concerning whether the volume or value standard can be violated only in situations where a physician's compensation fluctuates, the Proposed Rules state that the standard can be violated when a physician's payments are stable, but predicated (expressly or otherwise) on the physician making referrals. This interpretation is illustrated by the Proposed Rules which state that a condition of physician employment with a hospital which requires the physician to refer only within the hospital's own network of ancillary service providers violates the volume or value standard, even if the physician is paid a fixed salary, because the physician will receive no future compensation if he or she fails to refer. However, the volume and value standard is met where the physician is not required to refer within the network but chooses to do so on his/her own. In addition, the volume and value standard is not violated when a physician is required to refer within a network when the network entity is, through a risk-sharing arrangement, at substantial financial risk for the cost or utilization of the items or services.

c. *Commercially reasonable.* Many compensation-related exceptions include a requirement that the remuneration be commercially reasonable even if no referrals are made between the parties. The Proposed Rules interpret commercially reasonable to mean the appearance of a sensible and prudent arrangement from the perspective of the particular parties involved, even in the absence of any potential referrals.

1. *New compensation exceptions.* Current exceptions to the Stark Law restrictions do not fully encompass all fair market value or commercially reasonable compensation arrangements that are common in the provider community. In an effort to include these type of arrangements within the exceptions, the Proposed Rules create a new general exception for compensation

arrangements that are based on fair value and meet certain criteria. To meet this exception, an arrangement must:

- a. Be in writing, be signed by the parties, and cover only identifiable items or services, all of which are specified in the agreement;
- b. Cover all items or services to be provided or cross-refer to any other agreements for items or services to be provided;
- c. Specify the time frame for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one agreement during the course of a year;
- d. Specify the compensation that will be provided in the agreement, which must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals, payments for referrals for medical services not covered under Medicare or Medicaid, or other business generated by the parties;
- e. Involve a legitimate business purpose and be commercially reasonable; and
- f. Be in compliance with the federal illegal remuneration statute.

The Proposed Rules advise parties to use this exception when in doubt as to whether they meet the requirements of the other exceptions.

Recognizing that physicians often receive compensation in the form of incidental benefits that are not part of a written agreement, such as free samples or training sessions, the Proposed Rules also create a new exception allowing physicians and their family members to receive *de minimis* amounts of compensation without the risk of violating the Stark Law. This exception only applies to noncash items or services and specifically excludes gift certificates, stock or bonds, and airline frequent flier miles. To qualify as *de minimis* compensation, gifts cannot exceed a value of \$50 per gift with an \$300 per year aggregate limitation, and must be available to all similarly situated individuals regardless of whether these individuals refer patients to the entity for services. In addition, *de minimis* compensation cannot be based on the volume or value of referrals.

3. *Exception for bona fide employment relationships.* The Stark Law excepts from a "compensation arrangement" any amount paid by an employer to a physician (or immediate family member) who has a bona fide employment relationship for the provision of services if the arrangement meets certain standards. Under one of these standards, remuneration cannot take into account the volume or value of referrals by the referring physician. However, a physician or family member employee can receive a productivity bonus based on services personally performed by the physician or family member employee. The Proposed Rules modify the requirements for productivity bonuses paid to employees by adding the phrase "if the bonus is not directly related to the volume or value of a physician's own referrals." The preamble language indicates that allowing a physician to receive a bonus based on work actually performed, including designated health services that a physician refers to him or herself (e.g., professional radiology interpretation), permits the physician to profit from self-referrals. The language notes that the revision is necessary to equalize the bonus provision under the employment exception with that is found in the group practice definition, which provides that physician members of a group may receive productivity bonuses based on services personally performed, or services incident to personally performed services, as long as the bonus is not determined in any manner that is directly related to the volume or value of referrals by the physician. The Proposed Rules acknowledge that, unlike the group practice definition, the employment exception does not, by its terms, allow for indirect compensation based on profit sharing and productivity bonuses for a physician's "incident to" services; however, equalization of these provisions is not deemed necessary by HCFA.

4. *Exception for personal services arrangements.* The Stark Law excepts from the referral prohibition situations involving remuneration from an entity under a personal services arrangement if certain criteria are met. One criterion is that the arrangement cover all of the services to be furnished to the entity by the referring physician/immediate family member of the physician so that multiple contracts cannot be surreptitiously used to reward physicians for referrals. The Proposed Rules allow for the use of multiple agreements, provided that they incorporate each other by reference.

Furthermore, "personal services" are services of any kind performed personally by an individual for an entity or by technicians employed by the individual. "Personal services" arrangements cannot include equipment or other items if the arrangement is to meet the personal services exception since equipment arrangements must meet a separate exception for the rental of equipment. In addition, while the personal services exception requires that compensation not take into account the volume or value of any referrals or other business generated between the parties, situations involving a physician incentive plan between

the physician and entity are allowed. A physician incentive plan is any compensation arrangement where the physician or physician group is rewarded for limiting services to enrolled members. The Proposed Rules state that the incentive plan exception only applies when the entity involved is a type that enrolls its patients, such as an HMO. Thus, this provision would not be available to protect compensation paid by a hospital to physicians. The Proposed Rules also limit the personal services exception to arrangements with an individual physician (or family member) or a group practice. The new fair market value compensation exception could be available, however, to arrangements involving physician-owned entities that do not constitute a group practice.

5. *Exception for remuneration unrelated to the provision of designated health services.* The Stark Law provides an exception for remuneration by a hospital to a physician when the remuneration is unrelated to the provision of designated health services. The Proposed Rules construe this exception very narrowly, specifying that the parties must be able to demonstrate that the remuneration does not in any way involve designated health services nor reflect the volume or value of a physician's referrals for these services. If a physician is receiving payments that appear to be inordinately high for an unrelated item or service and also is making referrals for designated health services, it is presumed that the high payment relates to the volume or value of the physician's referrals. An example that would fall within this exception is a teaching hospital paying a physician rental payments for his or her house used as a residence for a visiting faculty member.

6. *Exception for a hospital's payments for physician recruitment.* The Stark Law excepts remuneration from a hospital to an individual physician that is used to induce the physician to relocate to the geographic area served by the hospital and to affiliate with its medical staff. This exception only applies to situations where the physician resides outside the geographic area and must actually relocate to join the hospital's staff. The Proposed Rules do not provide a definition of geographic area and solicit comments on this issue. The Proposed Rules also specify that payments to physicians residing within the geographic area (including residents completing a program in the hospital's area) and to groups in support of their recruitment efforts do not qualify for the recruitment exception, although they may qualify for the new fair market value compensation exception.

7. *Exception for certain group practice arrangements with a hospital.* The Stark Law excepts group practice arrangements that began before December 19, 1989, and have continued in effect since then without interruption. Since most arrangements do not remain constant over time, the Proposed Rules allow these arrangements to remain excepted even if the arrangement has changed so that it covers different services or the services are provided by different individuals within the same group practice. The group practice exception also requires that, with respect to the designated health services covered under the arrangement, substantially all of the services furnished to patients of the hospital be furnished by the group under the arrangement. The Proposed Rules interpret this standard to mean that whatever portion of a particular designated health service an agreement covers, the group must actually provide "substantially all," or at least 75 percent, of that portion.

8. *Exception for payments by a physician for items and services.* The Stark Law excepts payments that a physician makes to a laboratory in exchange for clinical laboratory services, and to another entity for other items or services if these are furnished at fair market price. The Proposed Rules interpret "other items or services" as any items or services other than clinical laboratory services, or those specifically listed under other compensation exceptions. Thus, a physician's payments for office space or equipment cannot fall within this exception.

9. *Exceptions for rental of office space and equipment.* The Proposed Rules address several issues relevant to the Stark Law exceptions for rental of office space and equipment. With respect to the minimum one-year term requirement, the Proposed Rules state that clauses that provide for early termination for good cause will not disqualify the lease as long as the parties do not enter into a new arrangement within the originally established one-year period. Leases must also be renewed in one-year increments. These comments also apply to services agreements with early termination or renewal clauses. The Proposed Rules also state that the lease exceptions would be invalidated if a lessee sublets office space or equipment because the lessee would no longer have sole access to the space or equipment, a requirement of the exceptions. The Proposed Rules state, however, that the new fair market value compensation exception could be potentially applicable to protect the lease and sublease. The Proposed Rules state that capital leases, which are similar to installment sales purchases in that the lessee receives the benefits of ownership (e.g., the ability to depreciate the property on its books as a capital asset), would not qualify for the lease exceptions. Finally, the Proposed Rules address situations

where equipment is leased on a service basis, stating that these arrangements could be valid if they comply with the fair market value and other standards included in the lease exceptions. However, to the extent that the lessor's payment reflects the volume or value of the lessor's own referrals, the rental payments cannot be computed on a per use basis for the lessor's patients.

10. *Sanctions*. The Stark Law provides that an entity may not present or cause to be presented a Medicare claim or a bill to any individual, third party payor, or other entity for designated health services furnished under a prohibited referral. Moreover, an entity that collects payment for a service furnished under a prohibited referral is required to refund all collected amounts on a timely basis. Civil money penalties of up to \$15,000 may be assessed on persons who:

- a. Present or cause to be presented a claim if the person knows or should know the claim is for a service furnished pursuant to a prohibited referral, or
- b. Fail to timely refund amounts collected.

The Office of Inspector General has published civil money penalty regulations which currently define a "timely basis" as 60 days from the time the prohibited amounts were collected. The Proposed Rules state that this requirement is being amended to specify that the 60-day period will begin when the individual or entity knew or should have known that the amount collected was related to a prohibited referral.

1. REPORTING REQUIREMENTS

Under the Proposed Rules, the reporting requirements under Stark Law would change in two ways S by relaxing the update provisions and by expanding the category of financial relationships subject to the reporting requirements.

The Stark Law requires entities providing Medicare-covered service to file reports that detail the ownership, investment, and compensation arrangements that could possibly expose such entities to a Stark Law violation. Under the Stark I Rules, entities must submit the required information on a HCFA-prescribed form and must provide updated information within 60 days from the date of any change. The prescribed form is still under development at HCFA. Recognizing the onerous nature of the update requirements, the Proposed Rules would require an update report only once per year. The annual update would report any changes that occurred in the previous 12 months. The Stark I Rules also exempt from the reporting requirement financial relationships that are protected by certain Stark Law exceptions. Thus, for example, if a hospital determines that a compensation arrangement is an excepted personal services arrangement, the hospital need not include this arrangement in its report. According to HCFA, this leaves the entity with the decision making power to determine whether a certain relationship is exempted. HCFA would like to claim such power to itself, and therefore, proposes to change the rules to require entities to report *all* financial relationships, including those that would probably fall into exceptions. HCFA recognizes that the burden associated with this new requirement "could be enormous," but announces its intent to "develop a streamlined reporting system that does not require entities to retain and submit large quantities of data." This streamlined system will require entities to keep only those records that include information an entity "knows or should know about, in the course of prudently conducting business." HCFA is currently developing a reporting form that will be published at a future date, and specifically has solicited comments on this proposal.

2. HOW THE STARK LAW APPLIES TO THE MEDICAID PROGRAM

The Stark Law prohibits the Secretary of Health and Human Services from paying federal financial participation ("FFP") to a state for designated health services furnished on the basis of a physician referral that would result in a denial of payment under Medicare if Medicare covered the services in the same way as the state plan. In the preamble to the Proposed Rules, HCFA indicates that, for purposes of the prohibition, the Medicare definition of physician, rather than the Medicaid definition, applies in determining whether an individual is a "physician." The Medicare definition of "physician" is more inclusive, and covers doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors, while the Medicaid definition of "physician" includes only doctors of medicine and osteopathy. Additionally, a physician does not have to participate in the Medicaid program for purposes of the prohibition.

According to HCFA's interpretation, the Stark Law does not, however, apply to Medicaid providers in the same manner it applies to Medicare providers. The Medicaid prohibition imposes

a duty on HCFA to review Medicaid claims, as if they were Medicare claims, and deny FFP to the state plan if a referral would result in a denial of payment under Medicare. As such, Medicaid providers are not precluded under the Stark Law from referring Medicaid patients or from billing for designated health services; however, a state cannot receive FFP for them. States may, of course, establish their own sanctions for physician self-referrals.

The Stark Law reporting requirements apply differently under the Medicaid program. Although the Stark Law states that certain information reporting requirements apply to a Medicaid provider in the same manner as to a Medicare provider, HCFA sets forth a distinction. Medicare providers are required under the Stark Law to furnish certain information (e.g., entity ownership, investment, and compensation arrangements) to HCFA. According to the Proposed Rules, Medicaid providers would be required to report similar information directly to the state, thereby "maintaining a symmetry between reporting in the two programs." This symmetry is due to the fact that the state is fulfilling the same payment function to Medicaid providers that HCFA fulfills with respect to Medicare providers.

3. CONCLUSION

The Proposed Rules clarify many issues regarding the expanded Stark II provisions, while raising many additional issues. The Proposed Rules solicit comments throughout many provisions. HCFA has considered provider comments in developing the Proposed Rules; thus, providers are encouraged to submit comments on issues relevant to their physician relationships. HCFA has extended the comment period under the Proposed Rules until May 11, 1998.