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MEMORANDUM

DATE: JANUARY 16, 2001
TO: CLIENTS AND FRIENDS
FROM: POWERS, PYLES, SUTTER & VERVILLE
RE: STARK II REGULATIONS

Long-awaited final regulations implementing the Stark II law were published in the Federal Register of January 4, 2001. Vol. 66 Fed. Reg. pages 856 to 965 ("the January 2001 rule," also referred to as the "final rule" or the "Phase I rule"). These regulations were first published in proposed form in January of 1998 ("the January 1998 proposal"), and apparently the Clinton Administration was anxious to get them out before leaving office. The final rule published last week, however, is only a partial rule, with some aspects of the 1998 proposal still awaiting final action in yet another rulemaking still to come.

This memo provides our initial analysis of the new rules and summarizes the state of Stark II as we understand it. For guidance concerning the applicability of this complex law to your particular arrangements, please contact any attorney at the Firm at 202-466-6550. For general information concerning this memorandum, please contact any of its authors -- Bob Saner, Becky Burke, Marla Spindel or Anthony Russo.

I. INTRODUCTION

A. Overview

The Federal physician self-referral law, generally referred to as the “Stark law,” generally prohibits a physician’s referral of a Medicare patient to an entity for the provision of certain designated health services if the physician has a financial relationship with the entity. The law is highly technical and complex, and has engendered both confusion and controversy throughout the health care industry. The confusion is based on the complexity of the statute itself, and the failure of the Health Care Financing Administration (“HCFA”) to adopt clear and concise regulations as to its applicability. The controversy lies in the simple fact that it either interferes with or regulates a broad array of business and professional arrangements between physicians and other health care providers, often in a manner that affects competition for delivery of ancillary services between physicians and other entities.

The Stark law is separate and distinct from the Federal anti-kickback law and other Federal fraud and abuse authorities which can also be implicated by physician financial arrangements with entities to which they refer Medicare and Medicaid patients. Compliance with the Stark law does not guarantee compliance with other fraud and abuse provisions, and compliance with those other fraud and abuse provisions does not guarantee compliance with the Stark law.

The regulations published January 4, 2001 answer many of the questions that have perplexed physicians, other providers, and their professional advisers for many years. In many respects, they do so in a more liberal and flexible manner than was the case under the January 1998 proposal. At the same time, the new rules remain highly technical, and HCFA provides roughly 100 pages of commentary accompanying their publication. Even with this detail, the January 2001 rule does not complete the regulatory scheme. As noted below, another Stark rulemaking is yet to come.

B. Statutory and Regulatory History

Congressman Pete Stark (D-CA) first proposed a Federal physician self-referral law in 1988, and what became known as “Stark I” was enacted by the Congress in 1989, at the same time Congress overhauled Medicare’s physician payment program and adopted the RBRVS fee schedule approach. The Stark I law applied only to clinical laboratory services and became effective with the fee schedule on January 1, 1992. HCFA proposed implementing regulations for Stark I in March of 1992, and these rules were finalized on August 14, 1995. They were codified at 42 C.F.R. 411.350 *et seq.*

Meanwhile, as part of a major package of Medicare and Medicaid amendments enacted in 1993, the Congress had significantly expanded the Stark law to cover a long list of designated health services in addition to clinical lab services. These amendments, which became effective January 1, 1995, became known as “Stark II.”

After a shift in control of the Congress in 1994, Congress reconsidered the statutory scheme it had just enacted. Legislation to significantly pare back Stark II was initiated by the House Ways and Means Committee in 1995, and was ultimately passed by both the House and the Senate as part of a large Medicare and budget bill. However, that bill was vetoed by President Clinton for other reasons, and the issue saw no further action on Capitol Hill for several years.

No implementing regulations were proposed for Stark II until January of 1998. In its January 1998 proposal, HCFA attempted to flesh out the regulatory scheme as applied to the Stark II's longer list of designated services, and in particular, as to the law's applicability to physician group practices. At the same time, HCFA issued implementing regulations establishing an advisory opinion process pursuant to which affected organizations can seek advance rulings from HCFA with respect to particular transactions and arrangements.

The January 1998 proposal was the subject of extensive public comment, and there was strong opposition from the physician community to many aspects of the rules. At the same time, industry representatives took their complaints with the statute and the proposed rules to Capitol Hill. Once again, legislation was introduced to significantly pare back the law. That legislation was not, however, acted upon by either the House or the Senate in the last Congress.

In responding to voluminous comments, and developing what became the January 2001 final rule, HCFA made a policy decision to bifurcate the final Stark II regulations into two phases. The January 2001 rule represents "Phase I." It deals extensively with the key definitions in the law, the provisions dealing directly with group practices, and the general exceptions which protect both ownership and compensation relationships, most important of which is the "in-office ancillary services" exception. In addition, Phase 1 adds several new compensation exceptions, some of which were not previously proposed. What HCFA has not finalized are most of the exceptions relating only to compensation arrangements, proposed in the January 1998 rule, as well as the exceptions which protect only ownership interests. Those provisions will be finalized in a new "Phase II," the future timing of which (like everything associated with Stark!) remains uncertain.

At the same time, by finalizing many of the law's key definitions, the Phase I promulgation does provide considerable guidance with respect to the reach of the law, interpretation of existing Stark I compensation exceptions, and the likely applicability of the Phase II compensation exceptions when finally promulgated.

C. Effective Dates

The Phase I regulations become effective one year after promulgation, or on January 4, 2002. Stark I regulations already codified, and not revised in Phase I, remain in effect, but technically only as applied to clinical laboratory services. Phase II rules, when they are promulgated, will presumably also have a prospective effective date.

With respect to those aspects of the law that HCFA has deferred to Phase II, the compliance status of particular arrangements or transactions will be governed by the statute itself. HCFA makes clear that the delay in promulgation of implementing regulations does not defer the statutory effective dates (January 1, 1992 for Stark I and January 1, 1995 for Stark II).

To date, there has been virtually no Federal enforcement of any aspect of the Stark law. Presumably, HCFA is signaling in this new Phase I rule its willingness to begin enforcement when this new guidance becomes effective, or sooner for clear violations of the statute. At the same time, a growing number of whistle-blower suits filed under the Federal Civil False Claims Act have raised Stark issues, asserting that a claim submitted in violation of Stark is a false claim for purposes of that other law. Thus, at the current time, enforcement by whistle-blowers and U.S. attorneys taking over whistle-blower initiated actions remains a greater practical risk than does any national enforcement initiative emanating from HCFA.

D. Comment Period on "Phase II Rule"

Despite the fact that many provisions of the January 2001 rule were noticed for public comment in the January 1998 proposal, HCFA is accepting public comments on everything in Phase I for 90 days (due April 4, 2001). HCFA indicates that these comments will be addressed and changes made, if any, at the same time the Phase II rule is promulgated.

E. Major Changes in Final Phase I Rule

The Phase I rule is different from the January 1998 proposal in many respects. In part, the changes respond to public comments submitted by the industry, and undoubtedly, in part, they respond to the threat of Congressional intervention. Many of the most controversial aspects of the January 1998 proposal have been significantly improved in the final product. While this memorandum does not attempt to cover each and every change between the proposed and final rules, some of the more significant changes would appear to be the following:

1. Personally Performed Services. HCFA previously proposed extending the law's referral prohibition and certain compensation restrictions to designated services, even if they were personally performed by the same physician who ordered them for his or her patient. The final rule effectively exempts personally performed services, even if on the designated list, from the reach of the law. This permits physicians to be paid on a productivity basis for designated services that they perform personally, even though they may have ordered them.
2. Indirect Compensation Relationships. It is clear from the statute that a financial relationship, for purposes of the Stark law, can be indirect, but it was not clear from the January 1998 proposal exactly how many of these indirect relationships would be treated. The final Phase I rule has a new definition of indirect financial relationships which provides protection to entities providing designated services if they did not know or have reason to suspect that a referring physician had an indirect relationship, and also provides a new exception for indirect compensation arrangements. While not easy to follow structurally, the final treatment of indirect financial relationships is certainly more generous than the January 1998 proposal.
3. "Volume or Value Test". A major uncertainty in 1998 was how services paid on a unit-of-service basis would be handled. The final rule, bowing to legislative history that accompanied the Stark II enactment, permits many fee-for-time or fee-for-service arrangements not clearly permitted under the January 1998 proposal.
4. The "Unified Business" Test. The proposal had a "unified business" test as part of the proposed definition of a bona fide group practice. The final retains certain aspects of the unified business test, but eliminates the most controversial feature, now permitting group practices to allocate income and expenses by site or specialty, and in some cases, even use separate ancillary compensation approaches by specialty and site.
5. The "Direct Supervision" Requirement. The proposed rule limited the availability of the in-office ancillary services exception by requiring direct (*i.e.*, in the suite) supervision for services provided by non-physician personnel. The final rule falls back to a more general supervision requirement, deferring to the particular supervision rules applicable for coverage and payment purposes. At some point in the future, this may create an even higher supervision standard for some services, if HCFA requires a higher standard for fee

schedule payment purposes, but at the current time, it generally provides a more relaxed standard for most services.

6. Productivity Bonuses and Profit Sharing in Group Practices. The final rule establishes several permissible compensation techniques, akin to “safe harbors,” for group distributions of revenues derived from Medicare designated services. While groups would much prefer repeal of the compensation test within the definition of group practice, the new rules provide substantial flexibility not found in the January 1998 proposal.

7. Designated Service Definitions. The final rule is certainly more precise, if not always more favorable, in defining the various categories of DHS services. The absurdly broad proposed definition of “physical therapy” services has come back to earth, and now covers services expressly listed by CPT code. Similarly, both the clinical laboratory and radiology definitions are handled by the listing of specific CPT codes. This resolves, generally favorably, uncertainty over the status of technical services which utilize imaging or ultrasound technologies, but which have not traditionally been thought of as radiology.

II. THE BASIC PROHIBITION

The law prohibits a physician from referring a Medicare patient for certain designated health care services ("DHS") to an entity with which the physician (or immediate family member) has a financial relationship through ownership or compensation, unless the self-referral is protected by one or more exceptions provided in the law. A companion provision of the Medicaid statute disallows Federal matching funds for state expenditures in connection with prohibited referrals. This provision requires implementing actions by the states before it is directly enforceable against provider entities for Medicaid referrals. The balance of this memorandum is focused on the Stark law's applicability to Medicare.

The basic prohibition is implemented in 42 C.F.R. § 411.353(a) of the Phase I rule. It applies to both direct and indirect financial relationships which physicians and family members have with DHS provider entities. The rule provides that a physician's financial relationship **will not be imputed** to his or her group practice, or other members or staff of the group practice. However, it also provides that the referrals of the group, other members or staff **may be imputed to the physician with the financial interest if that physician controls the referrals of others**.

Subsection (b) of 411.353 prohibits the DHS provider entity from billing Medicare, the patient, or anyone else if the DHS was provided pursuant to a prohibited referral. Subsections (c) and (d) provide that Medicare will not make payment for such a claim, and if payment is mistakenly made, the entity paid has a refund obligation. Subsection (e) provides an **"innocent payee" exception** if the DHS provider did not know or have reason to suspect the identity of the referring physician whose financial relationship would otherwise trigger the prohibition.

A. Financial Relationship

Section 411.354 sets forth detailed rules on covered financial relationships, including both direct and indirect ownership interests and compensation relationships. Subsection (b) of that section clarifies a number of uncertainties with respect to ownership and investment interests:

- **Secured debt** instruments are considered investment interests. Unsecured loans are not, but are compensation relationships.

- Ownership of a **subsidiary is not considered ownership of the parent**, or another subsidiary, unless the first subsidiary has an ownership interest in the parent or the other sub. These arrangements may be part of indirect financial relationships.
- Ownership of an interest in a **retirement plan** is not ownership of the provider entity.
- **Stock options** are compensation relationships until exercised, then they become ownership interests.
- **Under-arrangement contracts** between groups and hospitals do not create indirect ownership interests of the group's owners in the hospital. They are instead indirect compensation relationships.
- **Dividends, profit distributions and interest payments on secured debts** do not create separate compensation relationships if the investment interest on which they are paid qualifies for an ownership exception.
- **Indirect ownership interests** are covered if there is an unbroken chain of ownership interests between the referring physician and the DHS provider, regardless of the number of intermediate entities, **and the DHS provider knows or has reason to suspect the physician's (or family member's) indirect ownership.** Thus, even if the DHS provider knows the identity of the referring physician, if that entity has no reason to know of the physician's indirect financial relationship, the relationship is not covered, and no other exception is required to protect it.

Subsection (c) of 411.354 provides detailed rules on covered compensation relationships. Compensation can be any form of "remuneration," direct or indirect, between the physician or family member and the DHS provider. Remuneration is very broadly defined in § 411.351 to cover virtually any payment or other benefit, except for three categories specifically excluded:

- forgiveness of amounts otherwise owed in connection with **inaccurate or mistakenly performed tests or procedures**, or to correct **minor billing errors**;
- nonsurgical items and supplies provided **solely** for the **collection and handling** of test specimens, or solely for **test ordering or reporting** purposes;
- certain fee-for-service claims payments made to non-contracted physicians by health insurers or self-insured plans.

The Phase I Rule provides a new approach to "**indirect compensation arrangements.**" To be covered, the indirect arrangement has to have three elements:

- There must be an **unbroken chain** of financial relationships between the referring physician (or family member) and the DHS provider.
- The physician (or family member) receives **aggregate compensation** from the person or entity with which he has a direct financial relationship that **varies with or otherwise reflects the volume or value of referrals by the physician** to the DHS provider. If the referring physician's only direct financial relationship in the chain is ownership, then the volume or value test is applied to the compensation relationship closest to the physician's interest.
- The **DHS provider knows or has reason to suspect** that the physician receives aggregate compensation that varies with the volume or value of his referrals.

If any of the three elements is missing, the arrangement is not a covered compensation relationship for purposes of Stark, and it need not qualify for any exception.

Subsection 411.354(d) sets forth certain "**special rules on compensation.**" These rules apply only for Stark purposes, and are **key to understanding the difference between the Phase I rule and the January 1998 proposal. They will also be key to understanding the various compensation exceptions still to be promulgated in the Phase II rule.** They interpret more liberally than any previous HCFA rule or proposal the key questions of when a compensation relationship is "set in advance," whether it reflects the "volume or value of referrals," and whether it reflects "other business generated between the parties."

- Compensation is **set in advance** if it verifiably establishes **either aggregate compensation, time-based payment or unit-based payment** in the initial agreement, and is fair market value ("FMV") at the time of the agreement for the items and services to be provided, irrespective of current or anticipated referral volumes. **Percentage arrangements** are not set in advance if based on indeterminate or fluctuating factors (e.g., billings or collections), or result in different payments from the same purchaser for the same service. Percentage payments pegged to a fixed fee are permissible (e.g., X % of some fixed fee schedule).
- Compensation, including **even time-based or unit-based payment**, is **deemed not to take into account the volume or value of referrals** if FMV for items or services actually provided, and if it does not vary during the term of the agreement in a manner that takes into account DHS referrals.
- Once again, the rule **deems such arrangements not to take into account other business generated between the parties** if FMV, and if it does not vary during the term of the agreement in any manner related to the physician's referrals or other business, including non-Medicare business.

There is also a special rule permitting arrangements in which a physician's compensation is actually **conditioned on requirements to refer** to a particular provider, as long as the compensation is:

- fixed in advance;
- at FMV (not reflective of current or anticipated volumes);
- in compliance with either a general or a compensation exception;
- there is an explicit written agreement signed by both parties requiring the referrals to a particular provider; and
- the arrangement has escape valves for patient preference or payor choice of providers, and for medical judgement as to the best medical interests of the patient.

B. Covered Referrals for Designated Health Services

Whether a physician's financial relationship as defined in § 411.354 of the Phase I rule triggers the basic prohibition, and thus requires some exception, depends on whether the physician actually makes covered referrals of Medicare patients to the DHS provider for the provision of DHS services. Definitions of "referral" for purposes of Stark, and of the various categories of designated health services, are set forth in § 411.351 of the Phase 1 rule and are discussed under VI below.

III. GENERAL EXCEPTIONS PROTECTING OWNERSHIP, COMPENSATION OR BOTH

Section 411.355 of the rule provides for nine exceptions under this category, of which four were included in the January 1998 proposal, and five are newly added by the final rule.

A. Physician Services

The exception set forth in the statute for physician services is generally repeated in the final rule with the clarification that it applies not only to referrals to a member of the same group practice as the referring physician, but also to an independent contractor who qualifies as a physician "in" the group. In the preamble, HCFA explains that physician services personally performed by the ordering physician do not implicate the Stark law and, therefore, an exception for those services is not necessary.

B. In-Office Ancillary Services

The statutory exception for in-office ancillary services is the principal exception upon which most physicians rely to protect referrals for DHS within their own practices. As interpreted in the final Phase I rule, this exception has become more generous in some respects, and more restrictive in others. As HCFA has tried to provide direct guidance for a wide variety of different practice arrangements, it has certainly become more detailed and complex. Section 411.355(b) sets forth the basic requirements of the exception, and provides special rules for certain types of durable medical equipment ("DME") and for certain home care physicians.

The basic exception has three elements: a performance test, a site-of-service test, and a billing test.

1. The Performance Test. To be eligible for the in-office exception, the DHS must be performed by :

- the referring physician;
- another "member" of the same group practice;
- an individual who is supervised by the referring physician or another physician "in the group practice" (whether or not a "member" of the group).

For these and other purposes, a "member" is an owner or employee of the practice, whereas a physician "in the group" can be an independent contractor. Thus, the supervision requirement can be met by contract physicians, not just owners and employees. HCFA has also relaxed the standard, **dropping the "direct supervision" requirement** from both Stark I and the January 1998 Proposal in favor of whatever degree of supervision Medicare otherwise requires for coverage and payment purposes. In the short run, this will permit non-physician personnel to perform Medicare DHS without the need for physician presence "in the suite" for most services.

2. The Site-of-Service Test. The DHS must be furnished either:

- in the **same building** (but not necessarily the same part of the building) in which the referring physician or other member of the group provides **substantial** physician services that are **unrelated to DHS services, including non-Medicare DHS**. These unrelated services must represent **substantially the full range of services that the physician routinely provides**, and the receipt of DHS services **must not be the primary reason for the patient's contact with the referring physician or group**; or

- in the case of group practices, **in a centralized building** used by the group for the provision of some or all of the group's DHS.

These provisions are different from the January 1998 Proposal in several respects.

First, the "same building" test is more stringent because the "substantial" and "substantially full range" tests prevent a practice from qualifying an ancillary facility by simply providing token unrelated services there.

Second, the "same building" test is now tied to the relationship of the patient and the practice. If the patient comes only for DHS services, and not for professional services, HCFA does not consider those services ancillary to the practice.

Third, and favorably, HCFA has clarified that the "same building" for this purpose, can be a collection of interconnected buildings if they all share one street address; but, unfavorably, HCFA does not recognize driveways, parking lots or garages as being part of the same building, so that a van or trailer parked outside does not qualify as being in the same building as the professional offices inside.

Fourth, the new rule defines "centralized building" in §411.351 to require full-time use by the group claiming it, thus not permitting the same ancillary facility to qualify as "centralized" for more than one practice if shared through some leasing arrangement. On the other hand, the final rule eliminates the January 1998 proposal that a "centralized" facility serve more than one office of the same group practice. A group can have as many centralized facilities as it chooses, in any configuration, as long as they are owned by or leased full time by the group for its exclusive use.

3. The Billing Test. DHS services provided to Medicare patients must be billed by one of the following:

- the performing or supervising physician;
- the group practice of which he or she is "a member" under a billing number assigned to the group;
- the group practice of a supervising physician who is a "physician in the group";
- an entity wholly owned by the performing or supervising physician, or group practice under a billing number assigned to the physician or group; or
- a billing company functioning solely as an agent for one of the above, and billing under a number assigned to the physician or group.

The rule clarifies that a group practice may have more than one billing number assigned to it for this purpose.

4. Enteral and Parenteral Nutrition and Durable Medical Equipment. The statute makes the in-office ancillary exception available for all DHS services, except for parenteral and enteral nutrition, and DME, with a limited exception for infusion pumps. The final Phase I rule does not change the treatment of "P and E," so when those services are provided to Medicare patients pursuant to a self-referral, they must qualify for some other exception and may not utilize the in-office ancillary exception. The final rule's treatment of DME is considerably more complicated.

First, HCFA has created a new regulatory exception for certain DME products dispensed

in a physician's office. This exception applies to **canes, crutches, walkers and folding manual wheelchairs, plus blood glucose monitors** that meet the following:

- The patient must require the item for ambulation and use it in departing the physician's office, or in the case of a glucose monitoring device, it is furnished by a physician or employee or group practice that also furnishes outpatient diabetes training. The monitoring device may include one starter set of strips and lancets up to 100 of each.
- The DME item must be furnished in a building that meets the "same building" test as part of the same treatment for which the physician- patient encounter occurred. Group practices may not rely on the "centralized building" prong of the site-of-service test to qualify the DME items.
- The DME item is furnished personally by the ordering physician, another physician in the group, or by an employee of the physician or group. Supervision of other non-physician personnel (e.g., employees of another supply company) would not meet the "performance test" for this purpose.
- The physician or practice must meet all DME supplier standards.
- The arrangement does not violate the kickback law or any billing or claims requirement.
- The furnishing of the DME item meets all other requirements of the in-office exception (e.g., the billing test).

Second, the final rule clarifies the status of certain **pumps**. The statute permits use of the in-office ancillary service for infusion pumps that are classified as DME, and HCFA clarifies that this includes both the pumps implanted in the in-office setting, as well as external ambulatory infusion pumps that are fitted and filled at the office, even though used in the home. This protects most pumps used in cancer and pain therapy. However, pumps used for nutritional purposes are generally paid for as parenteral and enteral nutrition devices rather than DME, and they will not be eligible for the in-office exception.

5. Special Rules for Home Care Physicians. The Phase I rule provides a limited exception to the site-of-service test for referring physicians whose principal practice consists of treating patients in their private homes. For such a physician, the patient's home would be considered the "same building" as long as the physician or other person accompanying the physician provides the DHS service contemporaneously with a physician service that is not a DHS service. A nursing home or other facility is not considered the patient's home for this purpose.

C. Prepaid Health Plans

The final rule generally repeats the statutory exception for DHS furnished to enrollees of risk contract HMOs and certain other specified prepaid health care organizations that have entered into contracts with HCFA to offer such services pursuant to statutory mandates. HCFA clarifies that the exception not only protects referrals by physicians for DHS to a specified prepaid plan, but also protects referrals to downstream providers and suppliers furnishing these services under a contract with a prepaid plan. HCFA also has provided for a corresponding exception for so-called risk sharing arrangements, which is discussed in V below. Medicaid managed care arrangements will be addressed in Phase II of the rulemaking.

D. Services Paid Under a Composite Rate

HCFA has defined DHS in the final rule to exclude services paid by Medicare as part of a composite payment for a group of services, unless the DHS category is itself paid under a composite rate (e.g., inpatient or outpatient hospital services). Thus, while the Stark I exception for clinical laboratory services furnished in an ASC, ESRD facility, or hospice remains for services included in the ASC rate, the ESRD composite rate, or the hospice per diem rate, the Phase I rule does not need a comparable exception for other DHS services.

E. Academic Medical Centers

In the final rule, HCFA provides for a new exception for academic medical centers, to permit referrals from a physician to an academic medical center if certain conditions are met. First, the referring physician must: (a) be a *bona fide* employee of a component of the academic medical center on a full-time or substantial part-time basis; (b) be licensed to practice medicine in the state; (c) have a *bona fide* faculty appointment at the affiliated medical school; and (d) provide either substantial academic or clinical teaching services for which he or she receives compensation as part of his or her employment relationship with the center.

In addition, the total compensation paid for the previous 12-month period from all academic medical center components to the referring physician must be set in advance, must not exceed fair market value in the aggregate for the services provided, must not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties, and must not violate the anti-kickback statute.

Further, the academic medical center must ensure that: (a) all transfers of money between components of the center support the missions of teaching, indigent care, research, or community service; (b) the relationship of the center's components are set forth in a written agreement; and (c) all money paid to a referring physician for research is used solely for research.

F. Implants in an ASC

The final rule provides for a new exception for prosthetic and DME implants that are: (a) furnished by the referring physician or member of the referring physician's group practice in a Medicare-certified ASC with which the referring physician has a financial relationship; (b) implanted in the patient during a surgical procedure performed in the same ASC as where the implant was furnished; (c) furnished pursuant to an arrangement that does not violate the anti-kickback statute; and (d) billed and claimed in accordance with federal and state laws and regulations.

HCFA devised this exception to permit physicians to furnish implants in connection with surgeries performed in an ASC in which they have an ownership interest, recognizing that the new definition of DHS would not render this arrangement permissible because implants are not included in the bundled ASC facility rate.

G. EPO and Other Drugs Furnished in or by an ESRD Facility

The final rule provides for an exception for EPO and other specifically listed dialysis-related outpatient prescription drugs that are furnished in or by an ESRD facility, under an arrangement that does not violate the anti-kickback statute, and in accordance with Federal and state billing and claims submission laws and regulations. For purposes of the rule, the term "furnished" is defined to mean that the drugs are either administered or dispensed to a patient in

or by the ESRD facility, even if furnished at home. "Dialysis-related drugs" are defined as drugs required for the efficacy of dialysis.

H. Preventive Screening Tests, Immunizations, and Vaccines

Another new exception is available for preventive screening tests, immunizations, and vaccines that are covered by Medicare, identified by CPT and HCPCS codes, subject to HCFA-mandated frequency limits, and paid by Medicare on a fee schedule. In addition, the arrangement for the provision of these tests, immunizations, and vaccines must not violate the anti-kickback statute, and billing and claims for these items must be in accordance with applicable law and regulations. HCFA's stated reason for issuing this exception is to implement Congress' intent to provide preventive care for Medicare beneficiaries, and because it believes there is a low risk of fraud or abuse associated with the provision of items that are subject to frequency limits.

I. Eyeglasses and Contact Lenses

The final rule permits physicians to furnish eyeglasses or contact lenses to patients following cataract surgery in accordance with the Medicare coverage and payment provisions for the furnishing of such items. As with most of the other exceptions in this category, the eyeglasses or contacts must be furnished under an arrangement that does not violate the anti-kickback statute. Billing and claims submission for these items must comply with applicable laws and regulations. In providing for this exception, HCFA reasons that there is little risk of under or over-utilization because Medicare covers only one pair of eyeglasses or contacts after cataract surgery, and Medicare pays fixed amounts for these items regardless of their actual cost.

IV. BONA FIDE GROUP PRACTICES FOR PURPOSES OF STARK

Whether a particular combination of physicians is considered a bona fide group practice is critical for most practices to comply with the in-office ancillary service exception. This is one of the most confusing aspects of the statute, and was one of the most controversial issues in the January 1998 Proposal. The final rule provides both more certainty and more flexibility, and will minimize the overall impact of Stark on many practices. Once again, however, the requirements are very detailed and represent a degree of regulation of the structure and internal workings of group practices that is unprecedented in Medicare.

Section 411.352 of the Phase I rule finalizes the following requirements:

A. Single Legal Entity

The group must be a single legal entity:

- formed primarily to be a physician group medical practice;
- taking any organizational form recognized by state law;
- organized and owned by any individual or other legal entity, except another operating physician practice. Its owners may include individual PCs, or even PCs with multiple ownership, as long as they do not operate as medical practices. Its owners do not have to be physicians, or entities owned by physicians, but indirect physician owners of a group are counted as "members" of the group.

B. Two Physician Test

The group must have at least two physicians as owners or employees. Indirect physician owners count for this purpose, but independent contractors do not.

C. Full Range of Services Test

Each physician "member" of the group must furnish substantially the full range of patient care services that the physician routinely furnishes through the joint use of shared office space, facilities, equipment and personnel. As noted above, the rule excludes independent contractor physicians from the definition of "member," facilitating compliance with this test by groups that use independent contractors to perform specialized services.

D. Substantially All Services Test

At least 75 percent of the total patient care services of the group's members must be furnished through the group, billed under a billing number assigned to the group, with amounts received treated as receipts of the group. "Patient care services" is very broadly defined to include administrative and management services that benefit patients in general or the practice. This 75 percent test can be measured:

- by time and documented by any reasonable means, or
- by any other reasonable measure if fixed in advance, uniformly applied, verifiable and documented.

This test is waived for groups located in Health Professional Shortage Areas ("HPSAs") and applied differently if part of a physician's time is spent practicing in a HPSA.

E. Distribution of Income and Expenses

The statute requires that the overhead and income of the group be distributed in accordance with methods "previously determined." The proposed rule requires these methods to be determined prior to the time period during which the group earned the income or incurred the expenses. The final rule relaxes this slightly by requiring that the method be in place **prior to payment** for the service that generated the income or accompanied the expense. This permits frequent adjustments to allocation methods, as long they are effective prospectively, and as long as the compensation to physicians meets the compensation test discussed below.

F. Unified Business Test

The distribution test was complicated by the proposed rule's unified business test, which appeared to preclude separate cost and profit centers for different sites or specialties within a large group. The Phase I rule keeps this additional test, but relaxes it to require only:

- centralized decision-making by some governance group with control over assets, liabilities, budgets and compensation;
- consolidated billing, accounting and financial reporting; and
- centralized utilization review.

The final rule expressly permits decentralized compensation practices for non-DHS revenues, and even for DHS revenues if the compensation test below is met.

G. Compensation Test

The statute and the final rule start with a prohibition on compensation that is directly or indirectly related to the volume of value of a group physician's referrals, but then permit certain bonus and profit sharing practices that result in compensation being only indirectly related to referrals. The final rule is more favorable than either a strict reading of the statute or the January 1998 Proposal.

First, the compensation test only applies to Medicare DHS revenues.

Second, it does not apply to DHS services, even through Medicare, personally performed by the ordering physician since these are no longer referrals under the Phase I rule. It also appears, although there is some remaining ambiguity on this point, that a physician may get direct productivity credit for services performed "incident to," even though they are DHS services, but only if the services are billed and paid for under the "incident to" provision and not some other coverage category, and the physician meets all the "incident to" criteria -- originates the care to which the service is incident, is present in the suite and is immediately available.

Third, for profit sharing purposes, the "overall profits of the group" means only the profits derived from all Medicare and Medicaid DHS services of the group, or of any component of the group consisting of at least five physicians. This permits the distribution of Medicare ancillary profits by site, by specialty, or by any other grouping of at least five doctors within the practice.

Fourth, the rule sets out **three "safe harbor" profit sharing methods** as follows:

- per capita distribution of the overall DHS profits;
- distribution of DHS revenues on the same basis as revenues derived from sources other than Federal and private payor DHS services; or
- any method if less than 5% of the group's revenues comes from Medicare DHS services and no physician's allocation of Medicare DHS revenues exceeds 5% of his or her compensation.

This list is not exclusive. The rule permits any other "reasonable and verifiable" manner of distributing overall profits that is not directly related to the physician's volume or value of Medicare DHS services.

Fifth, the rule sets out **three similar productivity bonus "safe harbors"** and permits any other "reasonable and verifiable" bonus methodology that is not directly related to the physician's referrals.

H. Patient Encounters Test

Finally, the group practice definition includes, without addition or subtraction, the statutory provision requiring that members of the group personally conduct at least 75 percent of the physician-patient encounters of the group.

V. COMPENSATION EXCEPTIONS INCLUDED IN THE PHASE I FINAL RULE

The Phase I rule finalizes two exceptions for compensation arrangements that were in the January 1998 proposal and adds several new exceptions that HCFA created in response to public comments. It does not, however, have final rules for several of the statute's basic compensation exceptions, including those for space and equipment rentals, employment, personal services, purchased services and isolated transactions on which parties frequently rely to protect various arrangements. These remain to be completed in a Phase II rule. However, the Phase I treatment of key terms like "the volume or value of referrals" provides considerable relief with respect to these other compensation exceptions in the interim.

A. Non-Monetary Compensation up to \$300

HCFA has created an exception that protects non-cash gifts that do not exceed an aggregate of \$300 **per year** so long as the gifts:

- are not determined in any manner that takes into account volume or value of referrals or other business generated by referring physicians;
- are not solicited by the physician or the physician's practice (including employees and staff members); and
- do not violate the Federal anti-kickback statute.

HCFA eliminated the \$50 **per gift** from the January 1998 proposal. Thus, an entity can give a physician either one gift per year of up to \$300 in value or two or more gifts per year, as long as the annual aggregate value of the gifts does not exceed \$300.

B. Fair Market Value Compensation

Phase I includes the FMV exception from the January 1998 proposal, and because of the special rules governing compensation discussed in II. A. above, particularly the new rule on "volume or value of referrals," it is now much more accommodating. To qualify, arrangements must meet the following criteria:

1. be in writing, signed by the parties, and cover only identifiable items or services, all of which are specified in the agreement;
2. specify the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement for the same items or services during the course of a year. Arrangements for less than one year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change;
3. specify the compensation that will be provided, which must be set in advance. The compensation must be consistent with FMV and not be determined in a manner that takes into account the volume or value of any referrals or any other business generated by the referring physician, as those terms are now more loosely defined;
4. involve a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties;
5. meet a safe harbor under the anti-kickback law, be approved by the OIG under an

advisory opinion, or otherwise be in compliance with the kickback law; and

6. not involve the counseling or promotion of a business arrangement or other activity that violates State or Federal law.

Unlike the proposed rule, the final rule does not require that the written document cross-reference other agreements between the parties for other services.

C. Medical Staff Incidental Benefits

In response to public comment, HCFA added to the final rule an exception for non-cash items or services, provided by a hospital to members of its medical staff. This exception is available when the item or service is:

1. offered to all members of the medical staff without regard to the volume or value of referrals or other business generated between the parties;
2. offered only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital or its patients;
3. provided by the hospital and used by the medical staff members only **on the hospital's campus**;
4. reasonably related to the provisions of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital;
5. consistent with the types of benefits offered to medical staff members by other hospitals in the same region, or if there is no hospital within the same region, by comparable hospitals in comparable regions;
6. **less than \$25** with respect to each occurrence of the benefit;
7. not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties; and
8. not in violation of the kickback law.

This new exception protects items that would not meet the employment exception, because most members of a hospital's medical staff are not hospital employees, and would not qualify for the new FMV or other compensation exceptions, because there is no written agreement covering things like parking, coffee and donuts.

D. Risk Sharing Arrangements

The rule also provides a broad exception for risk-sharing relationships (withholds, bonus pools, etc.) between a managed care organization or IPA and a physician (either directly or indirectly through a subcontractor) for services provided **to enrollees of a health plan**. In order to qualify for the exception, the compensation arrangement cannot violate the Federal anti-kickback statute or any law or regulation governing billing or claims submissions.

E. Compliance Training

In an attempt to promote compliance training programs, HCFA added a new compliance training exception available for compliance training provided by a hospital to a physician who practices in the hospital's local community or service area, but only if the training is held in the local community or service area.

F. Indirect Compensation

Because many indirect compensation arrangements do not squarely fit in other compensation exceptions, HCFA added an indirect compensation exception in the final rule. This exception is available for any indirect compensation arrangement, as defined in section 411.354(c)(2) of the final rule (see II. A. above), if:

1. the compensation received by the referring physician is fair market value for services and items actually provided, not taking into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS;
2. the physician's compensation arrangement (or the compensation relationship in the chain of indirect relationships that is closest to the physician) is set out in writing, signed by the parties, and specifies the services covered by the arrangement. If the compensation relationship is one of bona fide employment, there need not be a written contract, but there must be identifiable services, and the arrangement must be commercially reasonable even if no referrals were made to the employer; and
3. the compensation arrangement does not violate the kickback law or any laws or regulations governing billing or claims submissions.

VI. OTHER KEY DEFINITIONS

Section 411.351 of the regulations defines the designated health services ("DHS") covered by the law, as well as other key terms.

A. Designated Health Services

In order for a referral to be covered under Stark II, it must be for one of the DHS listed in the statute. The final rule clarifies that, unless otherwise specifically stated, the term "DHS" means only a DHS that is payable, in whole or in part, by Medicare, but does not include services reimbursed by Medicare as part of a composite rate such as services provided by an ESRD facility or an ASC, unless the DHS category itself is paid on a composite rate (e.g. inpatient and outpatient hospital services). Referrals for DHS paid by private payors are not covered by the Stark law.

The rule provides additional clarification with respect to the individual DHS categories.

1. Clinical Laboratory Services. HCFA has defined these services by specific CPT and HCPCS codes. The initial list of covered codes is included as an attachment to the Federal Register notice and will be updated annually through HCFA's yearly physician fee schedule notice which is published every fall. The list will also be placed on a HCFA web site. Codes not included in the listing are not considered clinical laboratory services for

purposes of Stark.

The initial list includes all of the 80,000 series CPT codes except for certain blood component collection services and all HCPCS level 2 codes for other clinical laboratory services. The professional component of a clinical laboratory test is considered a DSH if it is listed as such in the code description.

The reference to specific codes should remove any ambiguity with respect to whether a test is covered by the Stark law.

2. Durable Medical Equipment. Durable medical equipment (“DME”) is defined by reference to the Medicare statute and section 414.212 of the Medicare regulations related to coverage. HCFA, in the preamble to the Stark II regulations, states that DME are all items classified as DME in the Durable Medical Equipment, Prosthetics/Orthotics and Supplies (“DMEPOS”) fee schedule. HCFA explains that those categories are mutually exclusive so no item can fall into more than one category. The distinction between DME and other similar items such as prosthetic devices is important because most DME does not qualify for the exception for in-office ancillary services. (See III.B.4. above.)

3. Home Health Services. Home health services are defined with reference to the coverage provisions of the Medicare statute and regulations. Essentially, they are services provided by Medicare-certified home health agencies that meet the coverage criteria for home health services. (See also VII. below.)

4. Inpatient and Outpatient Hospital Services. Inpatient and outpatient hospital services are defined by reference to payment and coverage provisions of the Medicare statute and include services of psychiatric hospitals and rural primary care hospitals. They also include services provided by others “under arrangement” with a hospital. Services of certain professionals, including physicians, nurse practitioners, and physician assistants, are excluded from the definition if they are paid separately (even if billed by the hospital under a reassignment) and not as part of the hospital inpatient or outpatient service.

5. Outpatient Prescription Drugs. The regulations define outpatient prescription drugs as all prescription drugs covered by Medicare Part B. This is broader than the January 1998 proposal, but certainly clearer. Under this more expansive approach, chemotherapy drugs, allergenic extracts, and any other drug, even if not self-administered, and even if prepared or mixed and furnished in the physician’s office, are DHS. There are limited exceptions for **EPO** and other drugs provided by ESRD facilities and for **certain preventive vaccinations and immunizations** if subject to Medicare frequency limits. However, many of these same drugs that are now DHS are eligible for the in-office exception under the final rule if dispensed in the physician’s office. HCFA also clarifies that physicians are not required to pass on drug discounts to Medicare, unless required by other laws.

6. Parenteral and Enteral (“P&E”) Nutrients, Equipment and Supplies. Parenteral nutrients, equipment and supplies are items and supplies needed to provide nutrition to patients with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength. Enteral nutrients, equipment and supplies are items and supplies needed to provide enteral nutrition to patients with functioning gastrointestinal tracts, who, due to pathology, cannot maintain weight and strength.

Referrals for “P&E” are not eligible for the exception for in-office ancillary services. HCFA specifically declined to create a further exception to permit self-referrals for P&E.

7. Physical Therapy, Occupational Therapy and Speech-Language Pathology Services. HCFA has defined these services with reference to specific CPT and HCPCS codes which are listed in an attachment to the Federal Register notice and which HCFA will place on a web site. The listing will be reviewed annually and published as part of the Medicare physician fee schedule rule. The current listing includes most of the physical medicine and rehabilitation codes in the 97,000 series of the CPT. Also included are cardiac rehabilitation codes, limb muscle testing and pulse oximetry if for the purpose of testing functional capacity. Electromyography (“EMGs”) are not included in the definition. If a service is not included in the listing, it is not a therapy service under this definition.

The definition in the final rule is much more narrow than the all-encompassing definition in the proposed rule.

8. Prosthetics, Orthotics and Prosthetic Devices and Supplies. HCFA’s approach here is similar to that taken with respect to the definition of DME. HCFA relies on the definition in section 1861 of the Medicare law and refers providers to the DMEPOS fee schedule. Items or services classified as prosthetics, orthotics or prosthetic devices and supplies (“O&P”) in that fee schedule will be considered such for purposes of the Stark law.

Orthotics are defined as leg, arm, back or neck braces listed in section 1861(s)(9) of the Act. **Prosthetics** are artificial legs, arms and eyes as defined in section 1861(s)(9). **Prosthetic devices** are devices (other than dental) that replace all or part of an internal body organ, including colostomy bags and one pair of conventional eyeglasses or contact lenses furnished with cataract surgery with the insertion of an intraocular lens. **Prosthetic supplies** are supplies necessary for the effective use of a prosthetic device (including supplies related to colostomy care).

HCFA notes that some O&P have HCPCS codes but are not in the DMEPOS fee schedule. If the item is not listed in the DMEPOS fee schedule, HCFA recommends that providers contact their carriers if they are unsure whether an item is considered O&P.

HCFA notes that **splints, casts and other devices** used to treat fractures and dislocations are not O&P and not a DHS because they are in a separate benefit category in the Medicare statute. HCFA also clarifies that O&P provided in an ASC and paid under the ASC facility fee, will not be considered O&P under the Stark law.

9. Radiation Therapy Services and Supplies. Services in this category are also specifically listed by CPT codes, and will be placed on a HCFA web site and reviewed annually. **Nuclear medicine procedures** are not included in the definition of radiation therapy services. In addition, HCFA states in the preamble that it has declined to exclude **prostate brachytherapy** from the definition of radiation therapy.

10. Radiology and Certain Other Imaging Services. Again, HCFA has opted to define this term with respect to specific CPT and HCPCS codes. The list includes the professional and technical components of any diagnostic test or procedure using X-rays, ultrasound, or other imaging services, computerized axial tomography (CAT scans) or MRI. It is drawn mostly from the 70,000 series of CPT, but also includes some echo, doppler and vascular

ultrasound codes from the 93,000 series, and a few HCPCS codes that involve radiology or other imaging technology.

It does not include certain imaging procedures that require the insertion of a needle, catheter, tube or probe (e.g., endoscopies and cardiac catheterization). Also excluded are radiology procedures integral to the performance of and performed during, nonradiological medical procedures, and screening mammographies.

B. Miscellaneous Terms

1. Consultation. The Stark law creates a narrow exception from the definition of “referral” for certain requests for DHS by pathologists, radiation oncologists or diagnostic radiologists if pursuant to a “consultation.” In this regulation, HCFA defines “consultation” as (1) a request by another physician for the physician’s opinion regarding a specialized medical problem; (2) the need for which is documented in the medical record; and (3) for which the consultant provides a written report to the requesting physician. For radiation therapy, a course of treatment meets the definition of consultation provided the radiation oncologist who communicates with the referring physician on a regular basis. Thus, the service does not necessarily have to be paid for as a consult.

2. Fair Market Value. This term appears in most of the compensation exceptions. The definition in the final rule is almost the same as the January 1998 proposal. It defines “fair market value” as the value in an arm’s-length transaction, consistent with the general market value. “General market value” is defined as the price an asset brings, or the compensation that would be included in a service agreement, as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party on the date of the acquisition or time of the service agreement. The fair market price is the price at which other sales have been consummated for similar assets in a particular market, and for services, the compensation included in other *bona fide* service agreements with comparable terms at the time of the agreement.

With respect to the exception for rentals and leases (which exceptions are not included in Phase I and will be addressed in Phase II), the regulations state that “fair market value” means the value of a rental property for **general commercial purposes** which **does not take into account its intended use**. The value of rental space may not be adjusted to reflect the additional value the lessee places on proximity or convenience to the lessor, if the lessor is a source of referrals to the lessee.

There is also new language in the definition of “fair market value” which states that a rental payment does *not* take into account intended use if it takes into account costs

incurred by the lessor in developing, upgrading, or maintaining the property or its improvements.

In the preamble, HCFA responds to questions related to how a provider should document fair market value. HCFA states that it will not give formal guidance and that documentation depends on the circumstances. However, the Agency notes that for rentals of office space, a list of comparables would be acceptable. Also acceptable, in some situations, would be an appraisal from a qualified independent expert.

3. Employee. The regulations define “employee” with reference to the IRS definition,

which in turn incorporates the state's common law test of employment. With respect to leased employees, HCFA, in the preamble, states that they could qualify as employees under Stark if they meet the IRS test.

4. Immediate Family Member. The Stark law prohibits referrals for DHS if the referring physician *or an immediate family member* has a financial relationship with the entity to which the service is referred. There is no change in the definition of this term from the 1995 regulations implementing Stark I. An immediate family member of a referring physician includes husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

5. "Incident to". The regulations define this term with reference to the requirements of section 1861(s)(2)(A) of the Act and section 2050 of the Medicare Carriers Manual. "Incident to" services are services provided by the physician or his or her employees in the office, under the physician's direct (in the suite) supervision.

6. Patient Care Services. The final rule defines "patient care services" to include any tasks performed by a physician in a group that addresses the medical needs of a specific patient, or of patients in general (regardless of whether they involve direct patient encounters), or that generally benefit a particular practice, even if administrative or managerial in nature. This term is relevant to the 75 percent test and the "full range of services" tests which are components of the definition of group practice. (See IV. C. and D. above.)

7. Referral and Referring Physician. A "referring physician" is a physician who makes a referral (as defined below) or who controls referrals made to another person or entity.

A "referral" is a request by a physician for, or the ordering of, or the certifying or recertifying of the need for, any DHS for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician. Also included in the definition of "referral" is the establishment of a plan of care which includes the provision of a DSH, and the certifying or re-certifying of a plan of care.

Significantly, HCFA has excluded from the definition of referral any DHS **personally performed** or provided by the referring physician. This is a major departure from the January 1998 proposal. Services performed by any other person, including the referring physician's employees, or other group practice members are not considered to be personally performed by the referring physician and thus would not be excluded from the definition of referral. (They might, however, be eligible for the physician services exception, or for treatment as "incident to" services in the group practice compensation test.)

As discussed above, certain referrals which are pursuant to a consultation by certain types of physicians are not considered referrals. (See discussion of consultations in VI. B. 1. above.)

VII. CERTIFICATION OF NEED FOR HOME HEALTH SERVICES

The final rulemaking has finally settled the running controversy between the application of the Stark rules and the pre-existing home health regulations that prohibited a physician from certifying plans of care for a home health agency if the physician had a significant ownership interest in or contractual or financial relationship with the agency. HCFA has determined that the Stark II law should supersede the previous home health physician certification law. According to the preamble, this revision in the law becomes effective on February 5, 2001, earlier than the deferred one-year effective date that applies to the rest of the final rule.

As a result, physicians who meet one of the exceptions of the Stark II law may have an ownership interest in or compensation arrangement with a home health agency. For example, a physician who meets the employment exception could receive compensation from a home health agency and still certify plans of care for that home health agency's patients. The exceptions to the previous home health physician certification law, *e.g.*, the 5 percent limitation on ownership by physicians and the sole community provider status for home health agencies, are no longer available.

See also III. B. 5. above for the special treatment of some home care physicians under the in-office ancillary exception.