STARK II:
AN OVERVIEW
LEGAL ANALYSIS OF
THE PHYSICIAN
SELF-REFERRAL LAW

The following pages are excerpted from a Powers, Pyles, Sutter, & Verville memorandum on the Stark II regulations. Phase I of the regulations were published in the January, 4, 2001, Federal Register. The memorandum provides the law firm’s initial analysis of the new rules and summarizes the Stark II regulations. For guidance concerning the applicability of this complex law to your particular arrangements, please contact any attorney at the firm at 202/466-6550. You can also visit the firm’s Web site at www.ppsv.com. The health care lawyers who authored this memorandum are: Bob Saner, Becky Burke, Marla Spindel, and Anthony Russo.
Section I: Introduction

Overview
The federal physician self-referral law, commonly 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 (DHS) 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. Many physicians and physician associations believe 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 between physicians and other entities for delivery of ancillary services.

The Stark law is separate and distinct from the federal anti-kickback law and other federal fraud and abuse regulations that 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 ensure compliance with other fraud and abuse provisions, and compliance with other fraud and abuse provisions does not guarantee compliance with the Stark law.

The regulations, published January 4, 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.

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 Congress in 1989. At the same time Congress overhauled Medicare’s physician payment program and adopted the resource-based relative value scale fee-schedule approach.

The Stark I law applied only to clinical laboratory services and became effective with the fee schedule on January 1, 1992. The Health Care Financing Administration (HCFA) proposed the implementation of regulations for Stark I in March of 1992, and these rules were finalized on August 14, 1995. They were codified in 42 C.F.R. 411.350 et seq.

Meanwhile, as part of a major package of Medicare and Medicaid amendments enacted in 1993, Congress significantly expanded the Stark law to cover a long list of DHS 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 Congress in 1994, Congress reconsidered the statutory scheme it had just enacted. In 1995, the House Ways and Means Committee initiated legislation to significantly scale back Stark II. The House and Senate ultimately passed this legislation as part of a large Medicare and budget bill. However, President Clinton vetoed the bill, and the issue saw no further action on Capitol Hill for several years.

Implementing regulations were not proposed for Stark II until January of 1998. In this proposal, HCFA attempted to flesh out the regulatory scheme as it applied to the Stark II’s longer list of DHS, and in particular, to the law’s applicability to physician group practices. At the same time, HCFA issued implementing regulations establishing an advisory opinion process allowing organizations to 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 scale back the law. That legislation was not, however, acted upon by either the House or Senate.

In responding to comments, and developing what became the January 2001 final rule, HCFA made a policy decision to split the final Stark II regulations into two phases. The January 4 rule represents “Phase I.” It deals extensively with key definitions,
provisions dealing directly with group practices, and the general exceptions that protect both ownership and compensation relationships, most importantly the in-office ancillary services exception.

What HCFA has not finalized are most of the exceptions proposed in the January 1998 rule relating only to compensation arrangements, as well as the exceptions that protect ownership interests. HCFA will publish these provisions in “Phase II,” of the final rule. It is unknown when HCFA will release Phase II.

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.

Effective dates
The Phase I regulations become effective January 4, 2002. Stark I regulations that were not revised in Phase I remain in effect but technically only as applied to clinical laboratory services. Phase II rules will likely 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 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 whistleblower 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. Thus, at the current time, enforcement by whistleblowers, and U.S. attorneys taking whistleblower cases, remains a greater practical risk than does federal enforcement.

Phase II rule comment period
HCFA had a 90-day public comment period (which ended on April 4) for Phase I of the rule. HCFA indicated that it will address these comments and it will publish any changes with the Phase II rule.

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. Some of the more significant changes include the following:

1. Personally performed services. HCFA previously proposed extending the law’s referral prohibition and certain compensation restrictions to designated services, even if the same physician who ordered them for his or her patient personally performed them.

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 they perform personally, even though they have ordered them.

2. Indirect compensation relationships. It is clear from the statute that a financial relationship, for the purposes of the Stark law, can be indirect. But it was not clear from the January 1998 proposal exactly how 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.

The definition also provides a new exception for
indirect compensation arrangements. Although 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 the 1998 proposal 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 proposed rule had a unified business test as part of the proposed definition of a bona fide group practice. The final rule retains certain aspects of the unified business test, but eliminates its most controversial feature.

It now permits group practices to allocate income and expenses by site or specialty, and in some cases, even to 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 nonphysician 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 distribution of revenues from Medicare designated services. Although 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. The broad proposed definition of “physical therapy” services has been tightened and now covers services expressly listed by CPT codes. Similarly, both 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 that utilize imaging or ultrasound technologies, but that have not traditionally been thought of as radiology.

**Section II: The basic prohibition**

The Stark law prohibits a physician from referring a Medicare patient for certain 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 basic prohibition (42 C.F.R. 411.353 [a]) applies to both direct and indirect financial relationships that 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) 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.

Breaking it down

**Financial relationship**
The final rule sets forth detailed requirements for covered financial relationships, including both direct and indirect ownership and compensation relationships. The rule clarifies the following uncertainties to ownership and investment interests:

- Secured debt instruments are considered investment interests. Unsecured loans are not, but are considered 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 subsidiary. These arrangements may be part of the 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 direct 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 if the DHS provider knows of 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.

Compensation can be any form of remuneration, direct or indirect, between physician or family member and the DHS provider. Remuneration is broadly defined to cover virtually any payment or other benefit, except for the following three specifically excluded categories:

- 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 noncontracted physicians by health insurers or self-insured plans

The Phase I rule provides a new approach to “indirect compensation arrangements.” It defines a covered indirect compensation arrangement between a physician and DHS provider as an arrangement that has the following three elements:

1. There must be an unbroken chain of financial relationships between the referring physician (or family member) and the DHS provider.

2. The physician (or family member) must receive 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.

3. The DHS provider must know or have reason to suspect that the physician receives aggregate compensation that varies with the volume or value of his referrals.
If the above three elements are part of an arrangement, then it is considered a covered indirect compensation arrangement and it must qualify for an exception to be permissible. If, however, any of the above three elements is missing from an arrangement, then the arrangement is not a covered indirect compensation arrangement and, therefore, it need not meet an exception to be permissible.

If the arrangement is neither a direct compensation arrangement nor a covered indirect compensation arrangement, then it does not implicate Stark and need not qualify for any exception.

The final rule also sets forth certain “special rules on compensation” that apply only for Stark purposes. These rules are key to understanding the difference between the Phase I rule and the January 1998 proposal. 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 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 (i.e., 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.

• Compensation, including time-based or unit-based payment, is deemed not to take into account the volume or value of referrals if services are provided at FMV and if it does not vary during the term of the agreement in a manner that takes into account DHS referrals.

• The rule deems such arrangements as not taking 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
• the compensation is at FMV and not reflective of current or anticipated volumes
• the compensation is 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
• the arrangement has escape valves for patient preference or payer choice of providers, and for medical judgment as to the best medical interests of the patient

Section III: General exceptions protecting ownership, compensation, or both
The final rule provides for nine exceptions under this category, of which four were included in the January 1998 proposal, and five were 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 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.

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

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 term, this will permit nonphysician personnel to perform Medicare DHS without the need for physician presence “in the suite” for most services.

Site-of-service test
The DHS must be furnished in one of the following places:
- 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.
- A centralized building used by the group for the provision of some or all of the group’s DHS in the case of group practices.

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 as 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 these 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. Unfavorably, HCFA does not recognize driveways, parking lots, or garages as being part of the same building—so 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” 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.

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

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

Enteral and parenteral nutrition and durable medical equipment (DME)
The statute makes the in-office ancillary exception available for all DHS services, except parenteral and enteral nutrition, and DME, with a limited exception for infusion pumps. The final Phase I rule does not change the treatment of parenteral and enteral. When those services are provided to Medicare patients pursuant to a self-referral, they must qualify for another 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 requirements:

• 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 must be furnished by a physician, employee, or group practice that also furnishes outpatient diabetes training. The monitoring device may include one starter set of up to 100 strips and lancets.

• 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" component of the site-of-service test to qualify for 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 (i.e., 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 anti-kickback law or any billing or claims requirement.

• The furnishing of the DME item meets all other requirements of the in-office exception (i.e., 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 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.

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's 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 that furnish these services under a contract with a prepaid plan. HCFA also has provided a corresponding exception for so-called risk sharing arrangements. Medicaid managed care arrangements will be addressed in Phase II of the rule.

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 (i.e., inpatient or outpatient hospital services). The Stark I exception for clinical laboratory services furnished in an ambulatory surgery center (ASC), end-stage renal disease (ESRD) facility, or hospice remains for services included in the ASC rate, the ESRD composite rate, or the hospice per diem rate. However, the Phase I rule does not need a comparable exception for other DHS services.

E. Academic medical centers
In the final rule, HCFA provides 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, (c) all money paid to a referring physician for research is used solely for research.

F. Implants in an ASC
The final rule provides 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. Epogen (EPO) and other drugs furnished in or by an ESRD facility
The final rule provides 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.

H. Preventive screening tests, immunizations, and vaccines
Another new exception is available for preventative screening tests, immunizations, and vaccines that are covered by Medicare, identified by CPT and
HCFA common procedure coding system (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 preventative 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 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 this exception, HCFA reasons that there is little risk of under- or overutilization 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.

Section 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. The final rule provides more certainty and flexibility and will minimize the overall impact of Stark in many practices. To qualify as a group practice, you must meet the following requirements:

A. 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 professional corporations (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% 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 broadly defined to include administrative and management services that benefit patients in general or the practice. This 75% test can be measured
   • by time and documented by any reasonable means
   • 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 an 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 required these methods to be determined prior to the time 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 allows frequent adjustment to allocation methods, as long as they are effective prospectively and 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
- centralized utilization review

The final rule expressly permits decentralized compensation practices for non-DHS revenues and 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 or 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 in the following five ways:

1. The compensation test only applies to Medicare DHS revenues.
2. 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.
3. 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, specialty, or by any other grouping of at least five doctors within the practice.
4. The rule sets out the following three “safe harbor” profit sharing methods:
   - Per capita distribution of overall DHS profits
   - Distribution of DHS revenues on the same basis as revenues derived from sources other than federal and private payer DHS services
   - Any method, if less than 5% of the group’s revenues comes from Medicare DHS services and none of the 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.

5. 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
The group practice definition includes, without addition or subtraction, the statutory provision requiring members of the group to personally conduct 75% of the physician-patient encounters of the group.