

PHASE I AND PHASE II STARK REGULATIONS

Summary of Interim final rules on Physicians Referrals to Entities to Which they have Financial Relationships (Stark II)

The Center for Medicare and Medicaid Services (CMS) published an interim final rule with a comment period regarding physicians' referrals to health care entities with which they have financial relationships (referred to as Phase 2) in the March 26th Federal Register. A copy of the rule is available at <http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/pdf/04-6668.pdf> The rule is effective on July 26, 2004. CMS will consider comments in response to the rule if they receive them by June 24, 2004.

The Phase 2 rulemaking addresses the remaining issues not addressed in the Phase I rulemaking (January 2001), and responds to public comments. This document summarizes the provisions in Phase I and Phase II of the rule that have the most significant impact on physical therapists.

Background

Section 1877 of the Social Security Act (the Act), also referred to as the physician self-referral law (Stark II) prohibits a physician from making referrals for certain designated health care services (including physical therapy services) to an entity in which the physician (or an immediate family member of the physician) has a financial relationship (ownership or compensation interest), unless an exception applies.

The health care services, (referred to as designated health services) to which the statute applies are: physical therapy services; occupational therapy services, radiology services and supplies; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. A financial relationship can be either an ownership interest or a compensation arrangement, and can be direct or indirect.

The law also prohibits an entity from billing for services provided as a result of the prohibited referral. There are a number of exceptions to the law, which are discussed in great length in the regulations.

The sanction under the Act is nonpayment of the service furnished under the prohibited referral. In addition, if the physician knowingly violated the Stark II laws, the physician would be subject to civil monetary penalties (CMPs).

The Stark II rule has been in effect since January 1, 1995. Proposed regulations were published in January 1998 (63 Fed. Reg. 1659). Phase I (which became effective on January 4, 2002) of the final rulemaking was published in the *Federal Register* on January 4, 2001 (66 Federal Register) as a final rule with comment period. Phase I became effective on January 4, 2002. APTA submitted extensive comments in response to the January 1998 proposed rule and the Phase I rulemaking. Phase I and Phase II of this rulemaking are intended to be read as a unified rule.

When is There a Financial Relationship Between the Physician and Entity?

The law defines a financial relationship as 1) an ownership or investment interest of a referring physician (or immediate family member) in the entity furnishing the designated health service (DHS); or 2) a compensation arrangement between the referring physician (or an immediate family member) and the entity furnishing DHS. The statute specifies that “financial relationships” include both direct and indirect ownership and investment interests and direct and indirect compensation arrangements.

Phase I

CMS defines a “direct” financial relationship to be an arrangement between the entity furnishing DHS and a referring physician or immediate family member with no person or entity interposed between them. With respect to “indirect relationships,” CMS states that exposure is limited to circumstances in which the “entity furnishing DHS has actual knowledge of an indirect financial relationship or acts in reckless disregard or deliberate ignorance as to the existence of an indirect financial relationship.” Thus, to satisfy the “knowledge” element in the case of an indirect ownership or investment interest, the DHS entity need only know or have reason to suspect that the referring physician has some ownership or investment interest in the entity furnishing the DHS (or in an entity that holds an ownership or investment interest in the DHS entity). Likewise, to satisfy the knowledge element in the case of an indirect compensation arrangement, the DHS need only know or have reason to suspect that the referring physician is receiving some aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.

Phase II

CMS retains the same definition that was included in Phase I, and clarifies that the entity need not know the precise composition of the chain or the specific terms of the investments in the chain, for an indirect ownership interest to exist.

Definition of Indirect Compensation Arrangement

Phase I

CMS develops a simple test to determine whether an indirect compensation relationship exists. They state that the arrangement must have three elements: 1) there must exist between the referring physician (or immediate family member) and the DHS entity an unbroken chain of persons or entities that have financial relationships between them meaning, each link in the chain has either an ownership or investment interest or compensation agreement with the preceding link); 2) the aggregate compensation received by the referring physician (or immediate family member) from the person or entity in the chain with which the physician has a direct financial relationship varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS; and 3) the DHS entity must have actual knowledge that the aggregate compensation received by the referring physician from the entity with which the physician has a direct financial relationship varies with, or otherwise reflects, the volume or value of referrals or the business generated by the referring physician for the entity furnishing DHS, or acts in reckless disregard or deliberate ignorance of the existence of such relationship.

Phase II

CMS retains the same definition that was included in Phase I.

Exception for Indirect Compensation Arrangements

Phase I

CMS recognizes that many indirect compensation arrangements may fit into statutory exceptions. Thus, CMS creates a new exception which would protect indirect compensation arrangements if the following conditions are met: 1) the compensation received by the referring physician (or immediate family member) from the person or entity in the chain with which the referring physician (or immediate family member) has the direct financial relationship is fair market value for the items or services provided under the arrangement and does not take into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS; 2) The compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement; 3) the compensation arrangement does not violate the anti-kickback statutes or any laws or regulations governing claims submission.

Where the financial relationship is an ownership and investment interest, CMS will apply the requirements of this exception to the first compensation arrangement in the chain of relationships between the physician and the entity furnishing DHS.

In the rule, CMS discusses how this would apply in the case of a physician's referrals to a SNF, which in turn, refers the patients to a PT company in which the referring physician has an ownership interest and which billed Medicare directly for services to SNF patients. In this example, the referring physician had a direct financial relationship (ownership) with the PT company. The referring physician has a referral arrangement with the SNF,

but not a financial relationship. The SNF has a referral arrangement with the PT provider, but not a financial relationship. The question this raises is whether by sending patients to the SNF, the physician is making referrals to the PT provider, which the physician has a direct financial relationship. CMS states that a physician can make a referral of DHS “to an entity” even though the referral is first directed through another person or entity, if the physician has reason to know the identify of the actual provider of the service. Thus, if the physician referring the patient to the SNF knows that the PT company in which he has an investment interest will furnish DHS to the patient or could reasonably be expected to know that the PC company will furnish the service, the referral to the entity is prohibited unless an exception applies. In addition, if the PT company knows or has reason to suspect that the referral for DHS came from a referring physician with whom the PT company has a prohibited financial relationship, the PT company cannot submit the claim for DHS.

Phase II

CMS retains the same definition that was included in Phase I.

When Does a Physician Make a Referral?

Phase I

The Stark II law defines a “referral” as a request by a physician for an item or service for which payment may be made under Medicare Part B, including a request for consultations, and the request or establishment of a plan of care by a physician that includes the furnishing of DHS.

In the Phase I final rule, CMS excludes services performed personally by the referring physician from the definition of referral (that is, the referring physician physically performs the service). Services performed by anyone other than the referring physician (whether an employee, a staff member, or a member of the physician’s group practice) would be considered referrals. They also specify that a referral can occur in a wide variety of forms, including written, oral, or electronic.

One commenter questioned CMS on whether referrals for DHS by a nonphysician professional employee of a group practice (e.g. nurse practitioner) would be imputed to a physician member of the group practice, when the nonphysician is authorized and licensed to prescribe treatment on his or her own. CMS responds by stating that the answer to the question will depend on the facts and circumstances surrounding the referral. The key question to ask is whether the physician controls or influences the nonphysician’s referral. CMS indicates that if the physician is controlling the referral, then it would be imputed to the physician.

Phase II

CMS retains the same definition that was included in Phase I.

In office ancillary services exception

The exception which enables most physician practices to refer Medicare patients for physical therapy services to entities in which they have an ownership interest or a compensation arrangement is the in-office ancillary services exception. This section summarizes that the requirements that must be met in order to qualify for the in office ancillary services exception. These include: 1) direct supervision; 2) building requirements; and 3) billing requirements.

Phase II

General Comments

In APTA's comments in response to the Phase I rule, APTA contended that these terms (direct supervision, building requirements, and billing requirements) should not be defined too broadly. If they are defined too broadly, they will result in abusive referral practices and will undermine the purpose of the Stark II law.

CMS states in the Phase II final rule that "several commenters objected to the easing of the requirements for meeting the in-office ancillary services exception. In particular, a number of physical and occupational therapy organizations complained that physicians would use the exception to expand the scope of the services they provide within their practice and thus capture additional revenues from their own referrals. In response, CMS stated that they believe that the final rule "reflects the balance that the Congress sought between regulating physician financial relationships and not unduly interfering with the practice of medicine."

1) Direct Supervision

Phase I

To qualify as an in-office ancillary services, the services must be furnished personally by a referring physician or another physician member in the same group practice or be furnished by individuals who are "directly supervised" by the referring physician or another physician in the group practice. In the proposed rule, CMS defined direct supervision as requiring that the physician be present in the office suite and immediately available to provide assistance and direction throughout the time services are performed. They would have allowed brief unexpected absences. CMS received numerous comments on this provision. Most of these commenters felt that this requirement was overly burdensome.

In the final Phase I rule, CMS amends its definition to state that "directly supervised" means that the supervision meets the supervision requirements under applicable Medicare and Medicaid payment or coverage rules for the specific services at issue. They believe that the legislative history of the law indicates that Congress did not intend to require physicians to be present at all times that ancillary services were being performed.

CMS also states that independent contractors would be able to provide the supervision required under the in-office ancillary services exception. They define physicians “in the group practice” to include owners of the group practice, employees of the group practice, and independent contractors, who are “in the group practice.” The independent contractor physician is considered “in the group practice” if he or she has a contractual arrangement to provide services to the group’s patients in the group practices facilities, the contract contains compensation terms that are the same as those that apply to group members; and 3) the independent contractor’s arrangement with the group complies with the reassignment rules.

One commenter stated that CMS, at a minimum, retain the “incident to” direct supervision standard, which was in the proposed rule. The “incident to” standard requires the physician to be in the office suite and that the individuals providing services be employees. The commenter was concerned about physician incentives to establish “backroom” practices to provide services that could be provided more efficiently elsewhere. CMS responded by stating that they share this commenter’s concerns about inappropriate financial incentives driving the provision of DHS. They are concerned that increased downward pressure on physician incomes will generate increased pressure to expand the in-office ancillary services to offset income losses. CMS notes that physicians wishing to bill DHS “incident to” must comply with the incident to supervision requirements, including the “present and available” requirement and the employee requirement as set forth in section 2050 of the Carriers Manual. However, they believe that it would be overly burdensome to require physicians, in all instances, to meet the stricter “incident to” supervision standard.

Phase II

In the Phase II rule, CMS summarizes questions raised by APTA using the following language:

- “When physical therapists work in a physician office, is the physician required to bill “incident to” for those services? Would the standards of Medicare Carrier’s Manual 2050 apply?”
- Does the level of supervision required in the physician’s office differ depending on whether a physical therapist has his or her own provider number?
- Can a group practice own a rehabilitation agency and bill through it? What is the supervision requirement?
- If a group practice owns a comprehensive outpatient rehabilitation facility (CORF), and the physicians who own the practice refer patients for physical therapy, what are the supervision requirements?”

CMS responds by stating that the Act should not subject physicians to supervision standards that differ from the standards for Medicare payment and coverage for the services provided. Thus, for example, services billed “incident to” will require the level of supervision applicable under the “incident to” rules. Services that require a low level general supervision will be subject to that lower level of supervision.

2) The Building Requirements

According to the Stark II law, in-office ancillary services must be furnished in a building in which the referring physician, or another physician who is a member of the same group practice, furnishes physician services unrelated to the furnishing of DHS. In the case of a referring physician who is a member of a group practice, the in-office ancillary services can be furnished in another building that is used by the group practice for the centralized provision of the group's DHS.

a) Same Building

Phase I

In the final rule, CMS defines a "building" as a structure, with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service. A building will be considered as one building for all suites or room numbers located inside with the same street address. The building consists of usable professional office space and common areas such as lobbies, corridors, elevator banks and restrooms. The "same building" does not include exterior spaces, such as courtyards, lawns, driveways, or parking lots, or interior parking garages. A mobile van or trailer is not a building or part of a building. The building could include a SNF or other facility or a patient's home.

CMS requires that the referring physician (or another physician who is a member of the same group practice) must furnish in the same building substantial physician services unrelated to the furnishing of Federal or private pay DHS, even if the physician service leads to the ordering of DHS. They are also requiring that the unrelated physician service furnished in the building represent substantially the full range of physician services unrelated to the furnishing of DHS that the physician routine provides (or, in the case of a member of a group practice, the full range of physician services that the physician routinely provides for the group practice). For example, a cardiologist who examines a patient and thereafter orders a diagnostic radiology test has performed a service unrelated to the furnishing of DHS. However, a cardiologist who reads the results of a diagnostic radiology test has performed a service that its related to the furnishing of DHS.

CMS adds a requirement that obtaining the DHS should not be the main reason the patient has contact with the referring physician (or his or her group practice). The standard is aimed at ensuring that self-referred DHS are ancillary and not primary services for the patients who receive them. Thus, for example, a physician who provides physician services and DHS for his or her patients in a nursing home may not also provide token physician services to other nursing home patients in order to provide those services under the in-office ancillary services exception.

CMS also states that the space in the building in which the DHS are provided does not have to be adjacent to the space in which the non-DHS services are provided. Also, shared facilities in the same building are permitted as long as they comply with

supervision, location, and billing requirements of the in office ancillary services exception.

CMS believes that a home care physician whose principal medical practice consists of treating patient in their private homes meets the “same building” requirements if the physician (or a staff member accompanying the physician) provides a DHS contemporaneously with the physician service.

Phase II

In the final Phase II rule, CMS continues the requirement (described in Phase I) that the building be one in which it has the same U.S. Postal address. However, CMS changes its test for determining whether services are unrelated to the furnishing of the DHS. CMS develops three new tests for determining whether physician services are unrelated to the furnishing of DHS (these replace the three part-test outlined in Phase I). According to CMS, a DHS is furnished in the “same building” if:

- 1) it is one in which the referring physician or his or her group practice has an office that is normally open to their patients at least 35 hours per week, and the referring physician or members of the group regularly practices medicine and furnished physician services to patients in that office at least 30 hours per week. Some of these services must be unrelated to the furnishing of DHS (although they could lead to ordering DHS) or
- 2) The service is furnished in the same building if the building is one in which the referring physician or his or her group practice has an office that is normally open to their patients at least 8 hours per week, and the referring physician regularly practices medicine and furnishes physician services to is or her patients in that office at least 6 hours per week (included unrelated services). In this test services provided by members of the group practice do not count toward the 6 hour threshold. Also, the building must be one in which the patient receiving the service usually sees the referring physician or other members of the group practice for non-DHS services. (the test generally describes a building where a referring physician practices medicine at least 1 day per week and that is the principal place in which the physician’s patients receive their physician services.
- 3) The building is one in which the referring physician or group practice has an office that is normally open at least 8 hours pre week, and the referring physician or member of the group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week in the office (including services unrelated to furnishing DHS). Also, the referring physician must be present and order the DHS during the time the office is open in the building or the referring physician or a member of the practice must be present while the DHS is furnished during the tie the office is open in the building. This test requires presence in the building, but not necessarily in the same space or part of the building. This test describes situations in which the referring physicians or group practice members provide physician services to patients at least 1 day per week and the DHS are ordered during a patient visit or the physicians are present during the furnishing of the DHS.

Physician services unrelated to the furnishing of DHS are defined to mean physician services that are neither Federal nor private pay DHS, even if the physician services lead to the ordering of DHS. For example, a physical examination that leads to an order for physical therapy.

2) **“Centralized Building”**

Phase I

CMS states that they believe the provision on “centralized buildings” was intended to allow group practices to have off site DHS locations in order to address concerns of group practices with multiple office locations that wanted to consolidate DHS operations for cost containment purposes.

A group practice may have multiple offsite locations for the centralized provision of services. CMS specifies to meet the requirements of the law the space must be used exclusively by the group, meaning it is wholly owned by the group practice or leased by the group practice on a full-time basis (24 hours per day, 7 days per week). Although shared facilities are allowed in the “same building,” group practice shared facilities in offsite buildings are precluded. The centralized building must be owned or leased exclusively by the group practice for at least 6 months. Also, part-time centralized DHS arrangements are precluded. Group practices may lease or sublease DHS facility space to or from other group practices or solo practitioners on a part-time basis, but DHS provided to patients of part-time lessee or sub lessee group practices will not fit in the in office ancillary services exception, unless the same building requirements are met.

Phase II

CMS retains the same definition as Phase I. Several groups, including APTA objected to CMS’s decision to permit group practices to have more than one centralized facility. In response, CMS states that they see no reason to restrict group practices to a single centralized building. They believe the requirement that any centralized building be owned or leased 24 hours per day, 7 days per week, for at least six months and used exclusively for the practice, protects against fraud and abuse.

3) **Billing Requirements**

To qualify for the in-office ancillary services exception, Phase I requires that the DHS must be billed by one of the following:

- The physician performing or supervising the service.
- The group practice of which such physician is a member, under that group practice’s billing number. CMS clarifies that group practices may have, and bill, under multiple group practice billing numbers.
- The group practice if the physician is a “physician in the group practice,” under that group practice’s billing number. This provision allows the group practice to bill for services provided by an independent contractor, who is considered a “physician in the

group practice.” The independent contractor would reassign his or her billing rights to the group.

- An entity that is wholly owned by the referring or supervising physician or the referring or supervising physician’s group practice. CMS clarifies that wholly owned entities that qualify to do the billing under the rule may use their own billing numbers and need not use a number assigned to the physician or group practice that owns them.

Phase II

In the Phase II rule, CMS summarizes and responds to the following questions posed by APTA.

- If a physical therapist employed by a physician practice furnishes services, bills using the physical therapy provider number, and then reassigns payment to the group practice are the billing requirements met?
- Would a rehabilitation agency which is owned by physicians, and has its own billing number be considered a wholly owned entity for billing purposes?
- Can physicians own a physical therapy private practice office and bill through the provider number of that office?
- When a designated health service is billed by an entity wholly owned by a group practice, do the Medicare conditions of participation applicable to the wholly owned entity determine the applicable level of supervision or do the supervision requirements related to the group practice billing apply?

CMS states that billing by a physical therapist under his or her own billing number does not satisfy the billing requirement of section 1877(b) (2) (B) of the Act. However, if the physical therapist reassigns his or her right to payment to the group, and the group bills using its own billing number (with the physical therapist’s billing number indicated on the bill), then the billing requirement would be met. The rehabilitation facility or physical therapy practice would be considered wholly owned if it is owned 100 percent by the physician group practice; 100 percent by the performing physician; or 100 percent by the supervising physician. A wholly owned entity can bill using its own billing number, and the supervision must meet the requirements applicable to the billing submitted to the Medicare program.

Definition of Group Practice

According to the law, a “group practice, is a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association, that meets certain conditions. The requirements that must be met to be considered a “group practice” are discussed in the paragraphs that follow.

1) Single Legal Entity Requirement

Phase I

CMS states that a group practice must be a single entity. A single legal entity can assume any form recognized by the State in which the entity gets legal status, including but not limited to a corporation (for profit, professional, or nonprofit), partnership, foundation, faculty practice plan, or limited liability company. The single legal entity can be legally organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities. The entity must be formed primarily for the purpose of being a physician group practice.

CMS identifies the following structures in the rule as qualifying as single legal entities:

- A partnership between two or more physicians.
- A partnership between one physician and another party, provided that the partnership employs at least one other physician. (Similarly, a partnership between two nonphysician parties can qualify if it employs at least two physicians).
- A corporation or limited liability company with one or more physician shareholders or members, provided that a corporation or limited liability company with only one physician shareholder or member employs at least one other physician.
- A corporation or limited liability company owned by nonphysicians provided it employs at least two physicians.
- A single legal entity owned by two or more physicians through their individual professional corporations.
- A solo practitioner who is organized as a legal entity and employs at least one other full-time physician.

CMS notes that this list is illustrative only, and that other variations are possible. A group practice does not include separate group practices under common ownership or control through a physician practice management company, hospital, or health care system, or other entity.

Several commenters asked CMS to clarify whether the “single legal entity” requirement precludes a group practice from having subsidiary entities that operate ancillary services. CMS stated that they believe that the statute does not preclude a single group practice from owning other legal entities for the purposes of providing services to the group practice. Thus, a group practice could wholly own and separately incorporate a laboratory facility that provides lab services to a group practice or other patients. The physicians could qualify for the in-office ancillary services exception as long as they meet the requirements for supervision, location, and billing.

CMS broadens the types of arrangements that qualify as a single legal entity to include multi-entity legal structures and structures owned by a single physician. CMS adopts a proposal to exclude independent contractors from the definition of “member of the group.” CMS expands the definition of patient care services to include all services a physician performs that address the medical needs of specific patients or patients in general or benefits the group practice (e.g. administrative services for the group). CMS revises the productivity bonus rules so that group practices may pay member physicians and independent contractors who qualify as “physicians in the group” productivity bonuses based directly on the physician’s personal productivity.

Phase II

CMS retains the same definition.

2. Members of the Group

Phase I

A member of the group practice is any physician who owns or is employed by the group practice. Independent contractors and leased employees would not be considered “members of the group”. The exclusion of independent contractors is intended to help group practice to comply with the “substantially all test.” However, independent contractors are considered “physicians in the group,” which enables them to provide the required “supervision” under the in office ancillary services exception.

CMS states that nonphysicians, such as nurse practitioners and physicians assistants, may be group practice “members” for general purposes, their membership will have no practice effect since they are not “physicians” for purposes of the three group practice “tests (the “full range of services,” “substantially all,” and “75 percent physician-patient encounters test), nor for purposes of profits and productivity bonuses. CMS notes that while referrals by nurse practitioners and physicians assistants generally do not trigger the Stark II law, which only applies to physicians, referrals by nonphysician health care professionals could implicate the statute if those referrals are directed or controlled by a physician. This means that physicians can’t circumvent the law by channeling referrals through nonphysicians.

One commenter suggested that a physician who opts out of, and is not receiving any payments from, the Medicare program should not be bound by the limitations in section 1877 of the Act, and thus would be able to refer to entities with which he or she has a financial relationship. The commenter asked whether the group physician’s opting out affects the ability of the rest of the group members to provide and bill for services they furnished to Medicare beneficiaries.

CMS states that a physician who opts out of the Medicare program and is not receiving any payments from the Medicare program is not bound by the limits of Stark II, and therefore, can refer to entities with which he or she has a financial relationship. The Stark II law prohibits only referrals for services for which payment would be made under Medicare. In this situation, payment is not made under the private contract. CMS

reiterates that when a group physician has opted out, it does not affect the ability of the rest of the group members to furnish and bill for services they furnish to Medicare beneficiaries. Also, the Medicare statute does not prevent an opt out physician's group from billing payers other than Medicare for services furnished under a private contract. Thus, a physician who opts out can remain a group member, provided the services are billed through the group practice to payers other than Medicare.

Phase II

CMS retains the same policy.

3) The Full Range of Services Test

Phase I

The definition of a group practice provides that each physician who is a member of the group must provide substantially the full range of services that the physician routinely provides, including medical care, consultation, diagnosis, or treatment through the joint use of shared office space. CMS clarifies in the final rule that "patient care services" include any physician's tasks that address the medical needs of specific patients or patients in general or that benefit the practice. According to CMS, these activities include, for example, time spent training group staff members, arranging for equipment, or performing administrative or management tasks, as long as these activities benefit the operation of the group practice. Services, which are wholly outside the group's medical practice, such as teaching, would not count as patient care services. This test is aimed at ensuring that a physician is actually practicing medicine and has not simply joined the group in name only.

Phase II

CMS retains the same policy.

4) The "Substantially All Test"

Phase I

Under the definition of a "group practice," substantially all of the services of the physician members must be provided through the group and billed under a billing number assigned to the group, and amounts received must be treated as receipts of the group. CMS interprets "substantially all" to mean that at least 75 percent of the total patient care services of the group practice members.

CMS clarifies that the "substantially all test" could be determined based on the member physician's actual time spent performing patient care services, whether it is performed inside or outside the practice.

CMS is not requiring that physicians use detailed time sheets or time cards. They state that appointment calendars, personal schedules, billing records, or other existing sources will be sufficient to establish the time spend on patient care services. CMS also says that group practices can adopt other means of satisfying the test if they are 1) reasonable; 2)

fixed services being measured (no ex post facto methods; 3) uniformly applied over time; and 4) verifiable.

CMS also states that independent contractors and leased employees are not defined under the final rule as members of the group. Thus, their services would not have to be counted in determining compliance with the substantially all test.

Phase II

CMS retains the same policy.

5) Unified Business Test

Phase I

The law requires that “the overhead expenses of and income from the group practice be distributed in accordance with methods previously determined.” CMS states that this requirement would be met if the method of distribution is determined prior to receipt of payment for the services. The methodology may be determined at any time until payment has been received, even if the income has been earned or costs incurred. The rule allows groups to adjust their methodologies prospectively as frequently as they determine is appropriate.

Phase II

CMS retains the same policy with slight modifications.

“Volume or Value” Standards

Many of the exceptions to the law require that compensation not take into account the “volume or value of any referrals. In addition some of the exceptions also require that the compensation not take into account other business generated between the parties. CMS interprets the statute as permitting time-based or unit-of service based payments, even when it is generated through a DHS referral, as long as it is set at fair market value at the beginning of the arrangement and does not subsequently change in any manner that takes into account the referrals.

Definitions Regarding Designated Health Services

Because there was much confusion pertaining to the definition of designated health services (DHS) under the proposed Physician Self-Referral rule, CMS has clarified this definition in the final rule. They have done this by publishing both a general explanation of the service and a specific lists of current procedural terminology (CPT) and CMS Common Procedure Coding System (HCPCS) codes that physicians and providers most commonly associated with a given designated health service. In the Phase I rule, CMS states that the list of codes will define the entire scope of the designated services category for purposes of section 1877 of the Act.

Below is a summary of these services. A list of the CPT and HCPCS codes that are used to define physical therapy, speech language pathology, and occupational therapy services is attached at the end of this document.

Physical Therapy and Speech-language Pathology Services

Phase I

In the Phase I rule, CMS chose to define physical therapy services by CPT codes. Also in the final rule, CMS states that physical therapy services include speech-language pathology services because 1861(p) of the Social Security Act includes speech therapy services in the definition of “outpatient physical therapy services.” Like physical therapy services, CMS uses CPT codes to denote those speech-language pathology services that fall within the category of designated health services. The list of speech-language pathology services was revised from the proposed rule to include the diagnosis and treatment of cognitive disorders including swallowing and other oral-motor dysfunctions.

Those physical therapy and speech-language pathology services that are included in a bundled payment such as skilled nursing facility (SNF) Part A services are not considered designated health services under the physician self-referral rule unless the statute so defines them. One example of services that are covered under a bundled payment that are defined as designated health services is home health service. This means that physician referrals regarding physical therapy services provided under the Medicare home health benefit are subject to the physician self-referral rule.

In response to public concern regarding physical therapists providing certain diagnostic testing such as electromyography (EMGs) and other measurements that some commenters feel fall outside of physical therapists’ scope of practice, CMS clarified that nothing in the proposed definition affected the scope of any practitioner’s practice. However, CMS further commented that they agree that therapeutic procedures such as nerve blocks and arthrocentesis are typically performed by a physician and are not generally considered to be part of physical therapy. Therefore, these procedures are not included in the list of CPT codes used to define physical therapy services for purpose of 1877(h)(6)(B) of the Social Security Act.

Furthermore, CMS clarified that the only pulmonary function test that may be considered to be a physical therapy service is pulse oximetry testing, CPT code 94762, when it is used to test for function capacity ratings. When oximetry testing is used to determine if a patient’s oxygen level is adequate for certain activities of daily living, then it is considered a physical therapy service.

Phase II

In comments to CMS, APTA expressed concern that CMS’s uses of the phrase “regardless who provides them” when discussing provision of physical therapy services, might imply that people other than licensed physical therapists and physical therapist assistants could provide physical therapy services in a physician’s office. APTA requested that CMS develop policies to avoid unlicensed or unqualified individuals from

providing physical therapy services. In response, in Phase II CMS states we did not intend the description of the term to have any effect on who is allowed to furnish physical therapy services to Medicare patients. The Stark II rules merely define the scope of services included in the definition; it does not address the qualifications required to perform them. CMS defers to existing Medicare policy concerning which professionals may provide a given service.

In its comments, APTA also notified CMS that they failed to include CPT code 97601 (wound debridement) and CPT code 97602 (non-selective debridement) in their list of physical therapy codes. In its response, CMS agrees to add these codes to the list used to define physical therapy services.

Finally, APTA asserted that CMS should not interpret the term “physical therapy services” to include speech-language pathology. In response, CMS states that it believes that by definition (based on the statute) speech-language pathology services are a subset of outpatient physical therapy under Medicare statute.

Occupational Therapy Services

Phase I

In the final rule, CMS states that occupational therapy services are based on those services defined in section 1861(g) of the Social Security Act and §410.100 c. However, CMS revised the definition from the proposed rule to include services for the “teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities.” As stated above for both physical therapy and speech-language pathology services, CMS intends to denote covered occupational therapy services with CPT/HCPCS codes. Furthermore, those occupational therapy services included in a bundled payment such as SNF Part A services will not be subject to the provisions in the final rule unless the statute states otherwise. In addition, CMS states that occupational therapy services may be furnished by an occupational therapist, an occupational therapy aide who is supervised by an occupational therapist, or by a physician.

Phase II

CMS retains the same definition.

Durable Medical Equipment (DME)

Because the public voiced concerns about difficulty discerning between DME items and prosthetic and orthotic devices, CMS stated that the distinction between the two of them is important because physicians may provide prosthetics and orthotics to patients under the in-office ancillary exception. However, the in-office ancillary exception does not apply to DME except in the case of infusion pumps. To determine if an item is considered DME or a prosthetic or orthotic, refer to the Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS) fee schedule that is available on CMS’s

website at www.CMS.gov/stats/pufiles.htm. CMS states that further questions should be referred to local carrier or durable medical equipment regional carrier (DMERC).

Within the DME definition section of the final rule, there were several questions regarding crutches. CMS clarified that crutches are DME and therefore definitely considered a designated health service. Because CMS believes that the inclusion of crutches under DHS may inconvenience patients who need them immediately following a treatment or procedure, CMS is expanding the in-office ancillary services exception to cover crutches contingent upon the physician realizing no direct or indirect profit from furnishing the crutches.

Phase II

CMS retains the same definition.

Prosthetics, Orthotics, and Prosthetic Devices and Supplies

In the proposed Physician Self-Referral rule, CMS included the following definitions: prosthetics: artificial legs, arms, and eyes as defined in section 1861(s)(9) of the Act; orthotics: leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act. Also, CMS defined “prosthetic device” as a device (other than a dental device) that “replaces all or part of an internal body organ, including colostomy bags and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each contact surgery with insertion of an intraocular lens, as well as services necessary to design the device, select materials and components, measure, fit and align the device, and instruct patients in its proper usage.” In addition, CMS proposed defining “prosthetic supplies” as supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).” In the final rule, CMS states this category, DMEPOS, includes all HCPCS level 2 codes for these services that are covered under Medicare.

Also, CMS responds to the public’s comments by clarifying that splints, casts, and other devices used to treat fractures and dislocations are not included in the DMEPOS benefit category and therefore, are not considered DHS. However, leg, arm, back, and neck braces are considered to be “orthotics” and are thus included as DHS. Rib belts and slings are not included in any DHS category, but basic braces are orthotics and therefore covered under the DHS umbrella. CMS confirms that a physician may furnish these items or services in his or her practice under the in-office ancillary services exception. CMS considers “furnishing an item” as dispensing the item to the patient in the physician’s office.

Other areas of concern pertain to knee implants. CMS states that they are considered prosthetics, and CMS states that both knee and artificial hip implants are included under DHS because they are provided as in-patient hospital services, a DHS.

Phase II

CMS retains the same definition.

Home Health Services

In the final rule, CMS removed the 5% ownership limit and the \$25,000 limit on financial or contractual relationships from section §424.22. The new §424.22 is more general. It states that the certification and recertification of the need for home health services may not be executed by a physician who has a financial relationship with the HHA as defined in §411.351 unless the physician's relationship meets one of the exceptions defined in §411.351 through §411.357. This requirement also applies to physicians who establish and review a home health plan of care for a HHA in which they have a financial relationship. The removal of the \$25,000 financial or contractual requirement relationship will allow an HHA to pay a physician medical director more than \$25,000 as long as the financial relationship meets a relevant ownership or compensation exception under section 1877 of the Act. **Unlike most provisions found in the final rule, this provision takes effect on February 5, 2001.**

CMS clarified that physicians providing physician services to home health patients do not constitute a home health service. Their visits would only qualify as such if they were providing a specific designated health service such as physical therapy. However, even in these cases, the service would not be covered under the DHS if the referring physician were providing the service because there would be no "referral" involved. In addition, some home health services provided by a home care physician may be protected by the in-office ancillary services exception.

Phase II

CMS retains the same definition.

Immediate Family Members

Phase I

CMS has retained its definition of "immediate family member" as it pertains to this rule. CMS defines an immediate family member as a: 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.

Phase II

CMS retains the same definition.

New Exceptions

In Phase I and Phase II of the rule CMS establishes new regulatory exceptions, which are not in the statute. The new exceptions include: Academic medical centers, fair market value, non-monetary compensation up to \$300 (and medical staff benefits). Several of the new exceptions are discussed below.

Exceptions for Fair Market Value

Phase I

CMS created an exception for compensation relationships that are based on fair market value and meet certain criteria. The criteria that must be met are:

- The agreement is in writing, signed by the parties, and covers identifiable items and services.
- The agreement specifies the timeframe for the arrangement, which can be for any period of time. The parties can enter into only one arrangement for the same items or services during the course of a year. An arrangement for less than 1 year may be renewed any number of times if the terms of the arrangement and compensation do not change.
- The agreement must specify the compensation, which must be set in advance, be consistent with fair market value (fair market value can be per click or per use, but not a percentage), 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.
- It must involve a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties.
- It must meet a safe harbor under the anti-kickback statute, is approved by the OIG under a favorable advisory opinion, or does not violate the antikickback provisions.
- The services performed under the arrangement may not involve the counseling or other activity that violates a State or Federal Law.

Phase II

Phase II does not substantively change fair market value exception outlined in Phase I. However, it revises the determination of “fair market value” regarding leases and hourly payments for physician’s personal services. In addition, one of the significant changes was to establish two methodologies for determining fair market value for physician’s services. If the methodologies are followed, then it will be deemed fair market value.

- With respect to rentals and leases, fair market value means value for general commercial purposes (not accounting for intended use), such value may not be adjusted to reflect the additional value of lessee’s proximity or convenience to lessor when lessor is a potential referral source.
- With respect to hourly payments, they would be deemed fair market value if established through either of the following methodologies: 1) hourly rate is less than or equal to average hourly rate for emergency room physician services in relevant market (must have 3 hospitals with ER market); or 2) hourly rate is determined by averaging the 50th percentile national compensation level for physicians with same physician specialty (or general practice if not specified) in the four surveys set forth in the rule.

3) Non-Monetary Compensation up to \$300 (and Medical Staff Benefits)

Phase I

Often, physicians and their immediate family members are given non cash items or services that have relatively low value and are not part of a formal written agreement. For example, a physician might receive flowers or free note pads from a provider. Although these discounted or free items would be considered a form of compensation, CMS believes that the compensation is not likely to cause overutilization if its nominal. Therefore, CMS proposes a new exception, the De Minimis Compensation exception. This exception allows physicians to receive compensation from an entity in the form of items or services that do not exceed \$300. Under this exception, an entity can give a physician one noncash gift per year valued up to \$300 or two or more noncash gifts per year, as long as the annual aggregate value of the gifts does not exceed \$300.

This exception only protects gifts to individual physicians. Thus, gifts given to a group practice would not qualify for the exception. However, noncash gifts could be given to one member, several individual members, or each member of a group practice. Each gift must meet all of the conditions of the exception. CMS states that the exception will not apply to gifts, such as holiday parties or office supplies, that are valued at less than \$300 per physician in the group, but are, given or used as a group gift.

CMS also states that gifts solicited by the receiving physicians or their group practice would not meet the exception. They do not want physicians to make noncash gifts a condition of doing business with a particular entity. The gift must involve a voluntary transfer made without the expectation of receiving any compensation in return.

Phase II

Phase II maintains the de minimis exception. It also establishes a provision updating the \$300 dollar amount annually for inflation based on CPI-U after September 30th each year.

Exceptions for Professional Courtesy

Phase I

No provision.

Phase II

In the Phase II rule, CMS creates a new exception for professional courtesy, which they define as the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff. To qualify for the exception, the following requirements must be met:

1. The professional courtesy is offered to all physicians on the entity's bona fide medical staff or in the entity's local community without regard to the volume or value of referrals or other business generated between the parties.
2. The health care items and services provided are of a type routinely provided by the entity;

3. The entity's professional courtesy policy is set out in writing and approved in advance by the governing body of the provider
4. The professional courtesy is not offered to any physician (or immediate family member) who is a Federal health care program beneficiary, unless there is a good showing of financial need;
5. If the professional courtesy involves any whole or partial waiver of coinsurance, the insurer is informed in writing of that reduction
6. The professional courtesy arrangement does not violate the antikickback statute or any billing or claims submission laws or regulations.

CMS clarifies that nothing in this exception prevents hospitals or other entities from extending their professional courtesy policies to employees, including nonphysicians. Additional, CMS cautions that these arrangements should not violate the antikickback statute.

Exception for Certain Arrangements Involving Temporary Non-Compliance

Phase I

No provision.

Phase II

Phase II establishes a new exception for arrangements that unavoidably and temporarily have fallen out of compliance with an exception. To comply the arrangement must have:

- Fully complied with another exception for 180 calendar days preceding date of noncompliance;
- Fallen out of compliance for reasons beyond the entity's control and the entity has taken steps to rectify the noncompliance;
- Otherwise complied with the antikickback statute and applicable laws and regulations;
- The noncompliance may not exceed 90 days.
- The exception does not apply to the de minimis exception.
- The exception may only be used once every 3 years by the same referring physician.

Exception for Intra-Family Rural Referrals

Phase I

No provision

Phase II

CMS creates an exception for intra-family rural referrals. According to the exception, a referral by a physician to a member of his or her immediate family or to an entity furnishing DHS with which the immediate family member has a financial relationship is excepted from the prohibition if:

- 1) The patient resides in a rural area

- 2) No other person is available to furnish the services 1) in a timely manner in light of the patient's condition 2) within 25 miles of the patient's residence;
- 3) For patients who receive services where they reside (e.g. home health or in-home DME), there is no other person available to furnish the services in a timely manner in light of the patient's condition, and
- 4) The financial relationship does not otherwise violate the antikickback statute, or any other federal or state law or regulation governing billing or claims submission.

The referring physician or immediate family member must make reasonable inquiries as to the availability of other persons or entities, but they do not have to make inquiries for entities that are greater than 25 miles from the patient's residence. Reasonable inquiry may include telephone directories, professional associations, other providers, or the Internet.

Reporting Requirements

Phase I

No provision included.

Phase II

The rule requires all entities, except those furnishing 20 or fewer Part A or B services in a calendar year, to submit certain information (e.g. name and UPIN of each physician who has a financial relationship with the entity and the nature of the relationship, to CMS or the OIG. However, this information is only required on request. They do not have to report financial relationships that fit into an exception. Failure to report may result in assessment of a civil money penalty of up to \$10,000 for each day.