HCFA Releases Phase I of the Stark II Regulations

On January 4, the Health Care Financing Administration (HCFA) released Phase I of the Stark II regulations. The Stark II law (42 USC 1395nn) prohibits referrals for designated health services by physicians (or their immediate family members) if they have a financial relationship with the health care entity to which they refer, unless an exception is met. It also prohibits submission of claims, as well as payment, for services resulting from prohibited referrals.

The proposed Stark II regulations were released January 9, 1998 and addressed ownership and investment interests, as well as compensation arrangements. Phase I of the final Stark II regulations addresses (i) the general prohibition on referrals, (ii) general exceptions to both ownership and investment interests and compensation arrangements, and (iii) pertinent statutory definitions. In addition, the new regulations provide several new exceptions: physicians at academic medical centers, fair market value transactions and indirect compensation arrangements, among others. Other sections of the Stark law, notably the remaining exceptions often relied upon by health care entities, the reporting requirements, application of the law to Medicaid, and applicable sanctions under the statute, will be addressed in Phase II of the final rule, which HCFA plans to release shortly.

Phase I is an interim final rule with a 90-day comment period. Most provisions are effective January 4, 2002.

Significant provisions of the new regulations impact the Stark law in the following ways:

**Designated health services.** The Stark II law and proposed regulations listed designated health services (see footnote 1) but did not define the listed services. The new regulations define the following services by specific CPT and HCPCS codes listed on the HCFA web site (and in annual updates published in the Federal Register):

- clinical laboratory services,
- physical therapy, occupational therapy, and speech-language pathology services,
- radiology and radiation therapy services (excluding x-ray, fluoroscopy or ultrasonic procedures that require insertion of a needle, catheter tube or probe through the skin or into a body orifice, radiology procedures that are integral to the performance of, and performed during, non-radiological medical procedures, and nuclear medicine procedures).
In addition, the new regulations provide specific definitions for the remaining designated health services as follows:

- **parenteral and enteral nutrients, equipment and supplies**: those items and supplies needed to provide nutriment to patients with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient’s general condition (parenteral) or needed to provide enteral nutrition to a patient with a functioning gastrointestinal track who, due to pathology to, or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition (enteral).5

- **prosthetics, orthotics, and prosthetic devices and supplies**: the following services,6 including all HCPCS level 2 codes for these services that Medicare covers:
  - orthotics: leg, arm, back and neck braces;
  - prosthetics: artificial legs, arms and eyes;
  - prosthetic devices: devices (except dental devices) that replace all or part of an internal body organ, including colostomy bags, and one pair of eyeglasses or contact lenses furnished after a cataract surgery with insertion of an intraocular lens; and
  - prosthetic supplies: supplies that are necessary for the effective use of prosthetic devices (including supplies directly related to colostomy care).

- **home health services**: home health services, as set forth in the Social Security Act and its related regulations, namely, part-time or intermittent skilled nursing services, physical therapy, occupational therapy or speech-pathology services, medical social services under the direction of a physician, part-time or intermittent home health aide services, medical supplies (excluding drugs and biologicals) and DME and services of interns and residents if the home health agency is owned by or affiliated with a hospital with an approved medical education program. Services that are not covered as home health services include: (i) drugs and biological, (ii) transportation, (iii) services that would not be covered as inpatient services, (iv) housekeeping services, (v) services covered under Medicare’s ESRD program, (vi) prosthetic devices, and (vii) medical social services provided to family members.7

- **outpatient prescription drugs**: all prescription drugs covered by Medicare Part B.

- **inpatient hospital services**: those services customarily provided to inpatients of a hospital including services furnished “under arrangement,” and inpatient psychiatric services and inpatient rural primary care hospital services. Inpatient hospital services do not include emergency inpatient services provided by a nonparticipating hospital within the U.S. or by a hospital located outside of the U.S., dialysis furnished by a hospital not certified to provide ESRD services, or professional services performed by other providers if Medicare reimburses the services separately rather than as part of the inpatient hospital service (even if the hospital bills for such services under assignment or reassignment).

- **outpatient hospital services**: therapeutic, diagnostic and partial hospitalization outpatient services, outpatient psychiatric hospital services, outpatient rural primary care hospital services, and services provided “under arrangement.” Outpatient hospital services do not include certain covered emergency services furnished in nonparticipating hospitals or professional services performed by other providers if Medicare reimburses the services separately
rather than as part of the inpatient hospital service (even if the hospital bills for such services are under assignment or reassignment).

Designated health services also do not include services that are reimbursed by Medicare as part of a composite rate (e.g., ASC services) unless the enumerated services are payable under the composite rate (e.g., home health and inpatient or outpatient hospital services).

**Physician referral.** Under Stark II, “referral” means the request by a physician for an item or service payable under Medicare Part B, including the request for a consultation with another physician and any test or procedure ordered by or to be performed by or under the supervision of that other physician. Under the new regulations, the definition of “referral” specifically excludes designated health services personally performed by the referring physician. Services are not “personally performed” if someone besides the referring physician (e.g., an employee, independent contractor or group practice member) performs them.

**Indirect financial relationships.** The Stark law includes in its definition of “financial relationships” both direct and indirect arrangements. With respect to indirect financial relationships, however, the new regulations add a knowledge requirement. Consequently, entities that provide designated health services and would otherwise be prohibited from seeking reimbursement under the Stark law, are not prohibited from seeking reimbursement unless the entity 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. Under the new regulations, the designated health services entity must (i) have actual knowledge that the referring physician (or immediate family member) has an indirect financial relationship (i.e., has (a) an ownership or investment interest in the entity or (b) receives aggregate compensation that takes into account or otherwise reflects referrals or other business generated by the referring physician or the entity furnishing designated health services), or (ii) acts in reckless disregard or deliberate ignorance of whether such an indirect financial relationship exists. Common ownership or investment in the same entity should be analyzed in the same manner as any indirect financial relationship. Additionally, an excepted financial relationship may still constitute a link in the chain that establishes an indirect compensation arrangement (ex., physician owns interest in hospital, hospital contracts for services with clinical lab, physician refers to lab—relationship between physician and lab is indirect and must fit test even though ownership interest is excepted).

The new regulations also define indirect compensation arrangements and create an exception for indirect compensation arrangements:

- **Definition of indirect compensation arrangement:** An indirect compensation arrangement is defined as follows: (i) unbroken chain of persons or entities that have financial relationships; (ii) aggregate compensation varies with or otherwise reflects volume or value of referrals or other business generated by the referring physician for the designated health services entity (per service or per use payment arrangements based in whole or in part on referrals or other business generated would satisfy this element); (iii) the designated health services entity has actual knowledge of the (ii) or acts in reckless disregard of that knowledge.

- **New exception for indirect compensation arrangements:** Arrangements between physicians and entities are permissible if (i) the compensation received by physician through direct financial relationship is fair market value and does not take into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing designated health services; (ii) compensation through the direct financial relationship is set out in writing, signed by the parties, and specifies the services covered by the arrangement (employment agreements need not be a written contract); and (iii) the compensation arrangement does not violate

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the anti-kickback statute or laws governing billing or claims submission.

- **In-office ancillary services exception.** Stark II excepts in-office ancillary services when the following conditions are met:
  - the services are furnished personally by (or under the supervision of) the referring physician, or by (or under the supervision of) a member of his/her group practice;
  - the services are furnished in a building that the referring physician (or member of his/her group practice) furnishes physicians’ services unrelated to the furnishing of designated health services, or in another building used by the group practice for the provision of some or all of the group’s clinical laboratory services or for the centralized provision of the group’s designated health services (other than laboratory services); and
  - the services are billed by the physician performing or supervising the services, or by the physician's group practice (under the group practice's billing number), or by an entity that is wholly owned by the physician or group practice and that meets other terms of Stark II.

The regulations expand the scope of this exception in the following significant ways:

- billing may be conducted by the physician performing the service, the group practice or a third party billing company, if proper provider billing numbers are used;
- the definition of supervision (pertinent to qualification as a group practice) conforms to other HCFA coverage and payment policies (direct supervision is no longer required);
- the location of services requirements of the exception may be satisfied by performing services in either: (i) the “same building” (defined by a single street address, and excluding mobile vehicles, vans or trailers) in which the referring physician provides the full range of services that are unrelated to designated health services, or (ii) a “centralized building” or mobile vehicle, van or trailer owned or leased on a full-time basis by a group practice for a term of at least six months and used exclusively by the group practice. Physicians providing care in their patient’s private homes meet the “same building” requirement if the referring physician (or qualified nurse or other person accompanying the physician) provides the designated health service contemporaneously with a physician service that is not a designated health service;

- the following durable medical equipment and prescription drugs may now be provided under this exception: canes, crutches, walkers, folding manual wheelchairs, blood glucose monitors, external ambulatory infusion pumps and chemotherapy infusion drugs dispensed in the physician’s office.

- **Group practice.** Under Stark II, referrals by members of a group practice to other members of the group are excepted when the group meets the group practice definition. Stark II defines a group practice as 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 in which:
  - each physician member of the group provides substantially a full range of physician services (medical care, consultation, diagnosis, treatment) through the joint use of shared office space, facilities, equipment and personnel;
  - substantially all of the services of the physician members of the group are provided through the group and amounts received for such services are treated as receipts of the group;
  - overhead expenses of and the income from the practice are distributed in accordance with methods previously determined;
  - no physician member of the group directly or indirectly receives compensation based on the
volume or value of referrals by the physician (unless permitted under Stark II as a profit or productivity bonus); and

- physician members of the group personally conduct no less than 75% of the physician-patient encounters of the group practice.

The new regulations provide that a group practice must be a single legal entity in any organizational form recognized by the state (including limited liability companies) that is formed primarily for the purpose of being a physician group practice and operating as a unified business. To operate as a unified business, the group must at least have: (i) centralized decision-making by a representative body of the group practice that maintains effective control over the group’s assets and liabilities (e.g., budgets, compensation and salaries), (ii) consolidated billing, accounting and financial reporting, and (iii) centralized utilization review.

The new regulations also provide that group practices may not be organized or owned (in whole or in part) by another medical practice that is an operating medical practice, and may not consist of informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control though a physician practice management company or other health care entity.

The group practice must have at least two physician members (employees or owners), and all physicians who are members of the group must provide the full range of services that physicians routinely provide (e.g., medical care, consultation, diagnosis, and treatment) through the joint use of shared office space, facilities, equipment and personnel. Group members must personally conduct (and document) at least 75% of the patient care services of the group11 (with an exception for groups located solely in health professional shortage areas), bill the services under a billing number assigned to the group, and treat payments received as receipts of the group.

Group income and overhead expenses must be distributed pursuant to preset formulae, determined before payment is received for the services giving rise to the income/overhead. Group practices may share profits and disburse productivity bonuses as discussed below. See “Percentage compensation arrangements; productivity bonuses.” Newly formed groups must make a good faith effort to comply with the group practice requirements within 12 months.

- New exceptions. The new regulations provide a number of new exceptions, which are summarized below:
  - Indirect compensation arrangements. Please see discussion above.
  - Fair market value arrangements. Arrangements between entities and physicians or groups of physicians (even those that do not meet the group practice exception) are excepted from the referral prohibition if: (i) the arrangement is in writing, signed and specifies the items or services covered; (ii) the arrangement specifies the timeframe and contains a termination clause, provided that the parties enter only one such arrangement for the same items or services in the same year (arrangements may be for less than one year, and, if for less than one year, may be renewed without limit if the terms and compensation for the same items or services do not change); (iii) the arrangement specifies compensation which is set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or any other business generated by the referring physi-
cian; (iv) the transaction is commercially reasonable and furthers legitimate business purposes; (v) the arrangement meets a safe harbor to the Anti-kickback Statute, has received a favorable OIG Advisory Opinion, or does not violate the Federal Anti-kickback Statute; and (vi) services under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates state or Federal law.

- **Academic medical centers.** The regulations create a new exception for academic medical centers where a physician has a bona fide employment relationship with a component of the medical center and a faculty appointment, is licensed in the state, provides substantial teaching services and is compensated for these services through the employment relationship. The referring physician's compensation arrangement must not violate the Federal Anti-kickback Statute. Additionally, total compensation for the previous 12-month period paid by all academic medical center components to the referring physician must be set in advance, and, in the aggregate, must not exceed fair market value, and must not be determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the academic medical center.

Finally, the academic medical center must meet specific conditions: (i) all transfer of money between components must directly or indirectly support the missions of teaching, indigent care, research or community service, (ii) the relationship of the components must be in a written agreement adopted by the governing body of each component, and (iii) all money paid to a referring physician must be used solely to support bona fide research.

- **Non-monetary compensation and medical staff benefits.** The regulations permit certain nominal, unsolicited non-monetary compensation to physicians (not exceeding $300 per year), and incidental benefits to medical staff members (less than $25 per occurrence) if available to all members of the medical staff and provided and used on the hospital campus.

- **Risk sharing arrangements.** The regulations create a new exception for risk sharing arrangements. Compensation under a risk sharing arrangement, including withholds, bonuses and risk pools, between a managed care organization or an independent physicians association and a physician (either directly or through subcontracts) for services provided to enrollees of a health plan is permitted if the arrangement does not violate the Federal Anti-kickback Statute or any law or regulation governing billing or claim submission.

- **Fair market value.** Fair market value is defined and will be evaluated with respect to similar transactions consummated at the same time. For example, with respect to rentals and leases, fair market value is the value of the rental property for general commercial purposes without consideration of intended use and without adjustment for proximity or convenience to a potential source of patient referrals. Costs incurred to develop, upgrade or maintain property or its improvements are not "consideration of intended use" under the definition.

- **Prepaid plan exception.** The regulations clarify that the prepaid plan exception is intended to protect downstream providers and defer consideration of extension of the regulation to Medicaid managed care until Phase II. The regulations also create a new exception for risk sharing arrangements (see above).

- **Percentage compensation arrangements.** The preamble to the regulations states that arrangements based on a percentage of gross revenues, a percentage of collections, or a percentage of expenses do not constitute compensation that is "set in advance." As a result, percentage com-
Compensation arrangements may be suspect under Stark II if they are based on a fluctuating or indeterminate amount. Compensation may however be time-based or per-unit-of-service-based, if the compensation is set in advance, constitutes fair market value, and does not vary based on volume or value of referrals during the course of the compensation arrangement. Additionally, the preamble states that percentage payments based on a single fee schedule would meet the set in advance requirement while a payment based on a percentage of multiple fee schedules (depending on the ultimate payer) would not meet the set in advance requirement.

- **Productivity bonuses.** The new regulations permit productivity bonuses or sharing in overall profits if such bonuses are for services personally performed (or “incident to” services personally performed), not related to the volume or value of referrals, and documentation of the method used to calculate the bonus is available to HCFA upon request. Shares of overall profits or productivity bonuses are not related to volume or value of referrals if at least one of the following is met:
  - the group’s profits are divided per capita or the bonus is based on the physician’s total patient encounters or relative value units;
  - revenues from designated health services are distributed based on the distribution of the group practice’s revenues attributed to non-designated health services payable by any Federal health care program or private payer, or the bonus is based on the allocation of the physician’s compensation attributable to services that are not designated health services payable by any Federal health care program or private payer;
  - revenues from designated health services constitute less than 5% of total revenues, and the allocated portion of those revenues constitutes 5% or less of each physician’s total compensation from the group; or
  - overall profits are divided or the bonus is calculated in a reasonable and verifiable manner that if not directly related to the volume or value of the physician’s referrals of designated health services.

- **Ownership or Investment Interests.** The preamble to the regulations clarifies that stock options and convertible securities are not ownership or investment interests until exercised or converted. Prior to exercise or conversion, however, stock options and convertible securities do constitute compensation arrangements.

- **Requiring referrals.** The regulations provide that physician compensation may be conditioned on the physician referring patients to a particular provider if the compensation arrangement is fixed in advance, consistent with fair market value, does not take into account the volume or value of anticipated or required referrals, and complies with an applicable Stark II exception, and the requirement to refer to a specific provider or facility is set forth in writing and does not apply if the patient asks for a different provider, the patient’s insurer determines the provider, or the referral is not in the patient’s best interest in the physician’s judgement. Importantly, any such arrangement should also comply with the Federal Anti-kickback Statute.

- **Revision of home health certification requirements.** The regulations revise certification and plan of treatment requirements for home health services. Physicians may not certify or recertify the need for services or establish or review a plan of treatment if the physician has a financial relationship with the home health agency, unless an exception to the Stark law is met.

- **“Incident to” services.** The regulations clarify that not all “incident to” services are included in the exception for physician services (e.g., diagnostic
tests and physical therapy services do not meet the exception).

- **Other.** Additional exceptions for specific items and services include preventive screenings, immunizations and vaccines, implants in an ASC, dialysis related outpatient prescription drugs, eyeglasses/contact lenses following cataract surgery, and certain services furnished under global rates (e.g., ESRD composite rate, ASC rate, per diem hospice charge).

Phase I of the new regulations provides important clarifications and means to achieve compliance with Stark II. Phase I of the new regulations also definitively states that compliance with its terms does not ensure compliance with, or exception or immunity from, other laws or regulations. (For example, meeting a Stark II exception will not serve as proof of compliance with the federal anti-kickback statute.) Accordingly, entities still must independently verify compliance with all applicable health care laws.

Given the bifurcation of the regulations, and the one-year time frame to transition into compliance, health care entities and physicians should review their relationships with each other, particularly those relationships based on percentage compensation. The differences between the proposed Stark II regulations and the Stark II interim final rule are extensive and demonstrate HCFA’s struggle not only with promulgating regulations for guidance but interpreting the existing statutory framework. Thus, health care entities and physicians should also consult counsel regarding existing and proposed arrangements to determine (i) the application of the statutory provisions of Stark II, (ii) the application to the statutory framework of the interpretive guidance provided in the commentary to the Stark II interim final rule, and (iii) the Stark II interim final rule itself (the latter which can be relied upon, for the most part, only after January 2002).

1 Designated health services are defined as: 1) clinical laboratory services, 2) physical therapy, occupational therapy, and speech-language pathology services, 3) radiology and certain other imaging services, 4) radiation therapy services and supplies, 5) durable medical equipment and supplies, 6) parenteral and enteral nutrients, equipment, and supplies, 7) prosthetics, orthotics and prosthetic devices and supplies, 8) home health services, 9) outpatient prescription drugs, and 10) inpatient and outpatient hospital services.

2 In accord with the Stark Law, references to physicians include the immediate family members of such physicians as appropriate.

3 The revisions to 42 CFR 422.24, related to home health certifications, are effective February 5, 2001. Note that according to media reports, President Bush has extended the effective date of rules recently published in the Federal Register for an additional 60 days.

4 The list of codes identifying the services includes outpatient physical and speech-language pathology services if the services include: (i) assessments, function tests and measurements of strength, balance, endurance, range of motion, and activities of daily living, (ii) therapeutic exercises, massage, and use of physical medicine modalities, assistive devices and adaptive equipment, (ii) establishment of a maintenance therapy itself is not covered as part of these services, and (iv) speech-language pathology services that are for the diagnosis and treatment of speech, language and cognitive disorders that include swallowing and other oral-motor dysfunctions, and occupational therapy services if the services include: (a) teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities, (b) evaluation of an individual’s level of independent functioning, (c) selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function, or (d) assessment of an individual’s vocational potential, except when the assessment is related solely to vocational rehabilitation.

5 These services are described more fully in the Medicare Coverage Issues Manual (HCFA Pub. 6), sec. 65-10.

6 These services are listed in the Social Security Act, section 1861(s)(8) and (9).

7 See Social Security Act section 1861(m); 42 CFR 409.49.

8 Outpatient hospital services are set forth in the Social Security Act, section 1861(s)(2)(B) and (C).
The request or establishment of a plan of care by a physician that includes the provision of designated health services also constitutes a referral. An exception to the definition also exists for requests for certain services by pathologists, radiologists and radiation oncologists if the services are furnished by or under the supervision of the pathologist, radiologist or radiation oncologist pursuant to a consultation requested by another physician. 42 USC 1395nn(h)(5).

For DME services to meet the exception they must be: (i) an item that a patient requires to ambulate, to depart from the physician’s office, or a blood glucose monitor and the physician or employee of the physician or group practice also furnishes outpatient diabetes self-management training to the patient, (ii) an item is furnished in a building that meets the “same building” requirements as part of the treatment for the specific condition for which the patient saw the physician, (iii) an item is furnished personally by the physician who ordered the DME, by another physician member in the group practice or by an employee of the physician or group practice, (iv) a physician or group practice meets all DME supplier standards, (v) the arrangement does not violate the anti-kickback statute or any law or regulation governing billing or claims submission, and (vi) all other requirements of the in-office ancillary services exception are met.

“Patient care services” may be measured by: (i) the total time each member spends on patient care services documented by reasonable means (time cards, appointment schedules, etc.), and (ii) any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable and documented.

An “academic medical center” consists of an accredited medical school, an affiliated tax-exempt faculty practice plan, and one or more affiliated hospitals in which a majority of the medical staff are faculty members and a majority of admissions are made by faculty member physicians.

“Overall profits” is defined as the group’s entire profits derived from designated health services payable by Medicare or Medicaid, or the profits derived from designated health services payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians.
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