



ICE MILLER'S WEBINAR

STARK LAW II – PHASE II INTERIM FINAL REGULATIONS

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STARK LAW II – PHASE II INTERIM FINAL REGULATIONS¹

I. STARK LAW

- A. Overview. The Stark Law prohibits a physician from referring Medicare (or Medicaid) patients to an entity in which the physician or a family member has a financial relationship for the provision of designated health services (“DHS”) unless the relationship fits a statutory or regulatory exception.
- B. Penalties. The Stark Law provides for the imposition of civil sanctions for violations including,
1. the denial of payment, refunds of amounts collected in violation of the statute,
 2. a civil money penalty of up to \$15,000 for each bill or claim for a service a person knows or should have know is a service for which payment may not be made, and
 3. a civil money penalty of up to \$100,000 for each arrangement or scheme which the physician or entity knows or should know has a principal purpose of assuring referrals which, if directly made, would be in violation of the statute.
- C. Designated Health Services.
1. clinical laboratory services;
 2. physical therapy services;
 3. occupational therapy services;
 4. radiology, including MRIs, CAT scans and ultrasound services;
 5. radiation therapy services and supplies;
 6. durable medical equipment and supplies;
 7. parental and enteral nutrients, equipment and supplies;
 8. prosthetics, orthotics and prosthetic devices;
 9. home health services and supplies;
 10. outpatient prescription drugs; and
 11. inpatient and outpatient hospital services.
- D. Regulatory History.
1. On August 15, 1995, the Centers for Medicare and Medicaid Services (“CMS”), in the U.S. Department of Health and Human Services (“HHS”) published the Stark I final regulations that covered clinical laboratory services retroactive to January 1, 1992 (60 Fed Reg. 41914).
 2. On January 9, 1998, CMS published the proposed Stark II regulation

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covering all DHS (63 Fed. Reg. 1659).

3. On January 4, 2001, CMS published Phase I of the final Stark Law regulation covering all DHS (the "Phase I Rule"). See 66 Fed. Reg. 856 *et seq.* The Phase I Rule, in general, became effective on January 4, 2002.
4. On March 25, 2004, CMS published Phase II of the Regulation (the "Phase II Rule"). See 69 Fed. Reg. 16054 *et seq.* The Phase II Rule was published as an interim final rule effective July 26, 2004. CMS is taking comments on Phase II issues through June 24, 2004.

II. EXCEPTIONS.

A. Exceptions Related to Ownership or Investment Interests.

1. publicly traded securities;
2. mutual funds; and
3. specific providers
 - a. rural providers,
 - b. hospitals located in Puerto Rico,
 - c. hospitals anywhere for designated health services provided by the hospital if the physician's ownership interest is in the entire hospital.

B. Exceptions Relating to Both Ownership/Investment and Compensation.

1. physician services [furnished personally by, or under the personal supervision of, another physician in the same group practice];
2. in office ancillary services;
3. services furnished by an organization to [prepaid health plan] enrollees;
4. academic medical centers;
5. implants furnished by an ASC;
6. EPO and other dialysis-related drugs furnished in or by an ESRD facility;
7. preventive screening tests, immunizations, and vaccines;
8. eyeglasses and contact lenses following cataract surgery; and
9. intra- family rural referrals.

C. Exceptions Related to Compensation Arrangements.

1. rental of office space;
2. rental of equipment;
3. bona fide employment relationships;
4. personal services arrangements;
5. physician recruitment;
6. isolated transactions;
7. certain arrangements with hospitals [unrelated to the provision of designated health services];
8. group practice arrangements with a hospital;

9. payments by a physician;
10. charitable donations by a physician;
11. non-monetary compensation up to \$300;
12. fair market value compensation;
13. medical staff incidental benefits;
14. risk-sharing arrangements;
15. compliance training;
16. indirect compensation arrangements;
17. referral services;
18. obstetrical malpractice insurance subsidies;
19. professional courtesy;
20. retention payments in underserved areas; and
21. community wide health information systems.

III. COMPENSATION AND BONUSES

- A. Under the Phase II Rule, all physicians may be paid using certain forms of percentage compensation and can receive a productivity bonus based on personally performed services.
 1. The Stark Law exceptions available for physician compensation depend upon the physician's status as a physician in a group practice, employee, or independent contractor.
 2. Statutorily, group practices receive favored treatment to divide revenue among the physicians in the group practice, regardless of whether the physician is an owner, employee, or independent contractor of the group practice. Other entities that provide designated health services, such as hospitals, are not permitted to share revenue to the same extent as a group practice.
 3. However, based on comments submitted for the Phase I Rule, the differences in the exceptions available for physician compensation have been minimized.
 4. *Percentage Compensation Arrangements:*
 - a. The exceptions for personal service arrangements, fair market value, and academic medical centers require that the compensation must be "set in advance".
 - b. Under the Phase I Rule, "set in advance" was interpreted to preclude most percentage compensation relationships.
 - c. Under the Phase II Rule, independent contractors and academic physicians can receive some forms of percentage compensation if the methodology for calculating the compensation is set in advance and does not change over the course of the arrangement in any

manner that reflects the volume or value of referrals or other business generated by the referring physician.

i. Specifically, compensation is now considered "set in advance" if:

(A) The aggregate compensation, a time-based or per unit service based (per-use or per-service) amount, or a specific formula for calculating the compensation is established in an agreement between the parties before items or services under the arrangement are provided.

(B) The formula is sufficiently detailed so as to be objectively verifiable and is not changed during the course of the agreement in any manner that reflects the volume or value of referrals or other business generated by the referring physician.

ii. Unit-based compensation (i.e., time-based or per unit of service compensation) will be deemed to not take into account "the volume or value of referrals" or "other business generated" by the referring physician if the compensation reflects the fair market value of the services or items provided and does not vary during the course of the agreement in any manner that takes into account referrals of designated health services or other business generated by the referring physician, including private pay health care business (except for services personally performed by the referring physician, which is not considered "other business generated").

d. The exceptions mainly available to independent contractors (the personal service arrangements and fair market value exceptions) require the following:

i. Personal Services Exception: Compensation paid by an entity under a personal service arrangement with a physician, an immediate family member of a physician or a group practice does not constitute a "financial relationship" if:

(A) Each arrangement is in a written agreement with a term of at least one (1) year, signed by the parties, and specifies the services covered by the arrangement. (If the arrangement is terminated during the term of the agreement with or without

cause, the parties may not enter into the same or substantially similar arrangement during the first year of the original term of the agreement.)

- (B) All of the services furnished by the physician (or immediate family member) to the entity are covered by the arrangement. If there is more than one arrangement, the separate agreements should incorporate each other by reference or cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. (The master list should be maintained so as to preserve the historical record of contracts.)
- (C) The aggregate services under the contract do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.
- (D) Compensation is set in advance, not in excess of fair market value, and (except for physician incentive plans) not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
- (E) The services provided under each arrangement do not involve counseling or promotion of a business arrangement or activity that violates Federal or State law.

ii. Fair Market Value Exception: Compensation paid for an arrangement between an entity and a physician (or an immediate family member) or any group of physicians for the provision of items or services to the entity does not constitute a "financial relationship" if:

- (A) The arrangement is in writing, signed by the parties, and covers only identifiable items or services that are specified in the written agreement.
- (B) A timeframe for the arrangement is identified in the written agreement, which may be for any period of time and contain a termination clause. (The parties may only enter into one arrangement for the same goods and services during the course of a year. An agreement for less than one (1) year can be renewed any number of times if the terms of the arrangement

and the compensation for the same items or services do not change.

- (C) The compensation for the arrangement is specified in writing, 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 other business generated by the referring physician.
 - (D) The arrangement is commercially reasonable and furthers the parties' legitimate business purposes.
 - (E) The arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claim submission.
- iii. Academic Medical Centers: The prohibition on referrals under Stark law does not apply to services provided by an academic medical center if:
- (A) The referring physician
 - (1) Is a bona fide employee of a component of the academic medical center on a full-time or substantially part-time basis;
 - (2) Has a license to practice medicine in the state in which he or she practices;
 - (3) Has a bona fide faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital; and
 - (4) Provides either substantial academic services or clinical teaching services (or a combination thereof) for which the faculty member receives compensation as part of the employment relationship with the academic medical center.
 - (B) The referring physician's total compensation paid by all academic medical center components is set in advance and, in the aggregate, does not exceed the fair market value of the physician's services, and is not 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.

(C) The academic medical center itself meets certain requirements.

(D) The compensation arrangement with the referring physician does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

5. Productivity Bonuses

a. Under Phase II Rule, all physicians can be paid a productivity bonus based on work they personally perform.

b. The Phase II Rule clarifies that, under the exceptions for personal services arrangements, fair market value, and academic medical centers, compensation may not take into account "other business generated" by the referring physician, which includes the technical components of a service billed by a entity providing designated health services.

c. Under the exception for in-office ancillary exception, physician groups have additional latitude to pay physicians in a group based on "incident to" services, indirect bonuses, and profit shares that may include revenue from designated health services.

IV. IN-OFFICE ANCILLARY EXCEPTION.

A. The exception for in-office ancillary services has been modified in the Phase II Rule to simplify the "building" tests and make certain minor changes in response to comments received in response to the Phase I Rule.

1. Three new tests for meeting the "same building" requirement of the exception are provided in the Phase II Rule; only one of the three tests must be meet to satisfy the "same building" requirement.

2. The Phase II Rule eliminates the requirement that unrelated DHS must represent the full range of physician services unrelated to the furnishing of DHS that the referring physician routinely provides.

3. Another change in the Phase II Rule is that a patient's primary purpose for contact with the referring physician can be for the receipt of DHS.

B. The in-office ancillary exception excludes certain services (including certain items of durable medical equipment ("DME")) that are ancillary to the medical services provided by the physician's practice from the prohibition on referrals. To

fit within the exception, the services must meet conditions regarding who furnishes the services, where the services are furnished, how the services are billed.

1. Furnishing services:

- a. The in-office ancillary services must be provided by one of the following individuals:
 - i. The referring physician;
 - ii. A physician who is a member of the referring physician's group practice; or
 - iii. An individual who is supervised by the referring physician or, if the referring physician is in a group practice, by another physician in the group practice. (The supervision must comply with the applicable Medicare payment and coverage rules for services.)
- b. DHS services are "furnished" in the location where the service is performed upon the patient or the item is dispensed to a patient in a manner sufficient to meet the Medicare payment and coverage rules.

2. Location of services: under the exception, ancillary services must be furnished in the same building as non-DHS physician services or, if the referring physician is in a group practice, in a centralized building.

- a. Definition of the "same building":
 - i. A structure (or combination of structures that share) a single street address designated by the U.S. Postal Service.
 - ii. Does not include mobile vehicles, vans, trailers, interior loading docks or parking garages or exterior spaces, such as lawns, driveways, and parking lots.
- b. The services must be provided in one of the following locations:
 - i. The "same building" that meets one of the following tests:
 - (A) The building is one in which the referring physician or group practice has an office that is normally open to patients at least thirty-five (35) hours per week, and the referring physician or group practice members regularly practice medicine and provide physician services to patients at least thirty (30)

hours per week, which must include "some" services that are unrelated to furnishing DHS payable by Medicare, any other Federal health care payer or a private payer.

(B) The patient receiving the DHS usually receives physician services from the referring physician or, if applicable, members of the physician's group practice; the referring physician (or the referring physician's group practice) owns or rents an office that is normally open to the physician's (or group's) patients for medical services at least eight (8) hours per week; and the referring physician regularly practices medicine and furnishes physician services at least six (6) hours per week, which "some" services that are unrelated to furnishing DHS payable by Medicare, any other Federal health care payer or a private payer. (Note that the referring physician must personally perform at least six (6) hours per week of services unrelated to furnishing DHS.)

(C) An office that the referring physician (or his/her group practice) owns or rents that is normally open to the physician's or the group's patients for medical services at least eight (8) hours per week, and referring physician or one or more members of the group practice regularly practices medicine and furnishes physician services at least six (6) hours per week, which "some" services that are unrelated to furnishing DHS payable by Medicare, any other Federal health care payer or a private payer.

(1) Note that under this test, it is either the referring physician or one or more group practice members who must personally perform at least six (6) hours per week of services unrelated to furnishing DHS.

(2) The referring physician must be present and order the DHS during a patient visit to an office described in (II)(B)(2)(b)(i)(C) above or the referring physician or a member of the referring physician's group practice must be present while the DHS is furnished to the patient during the occupancy of such an office.

- ii. A centralized building used by the group practice for providing some or all of the group's clinical laboratory services. (A "centralized building" means all or part of a building, including a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (24 hours per day, 7 days a week for at least a 6 month period) by a group practice and exclusively used by the group.)
 - iii. A centralized building used by the group practice for the provision of some or all of the group's DHS, other than clinical laboratory services.
 - c. If a referring physician's principal medical practice consists of treating patients in their private homes, the "same building" requirement is met if the referring physician (or qualified person accompanying the physician) provides the DHS contemporaneously with a non-DHS service to the patient in the patient's home. A patient may have a "private home" in an assisted living or independent living facility, but not in a nursing, longer care, or other facility or institution, for the purposes for determining where a DHS is furnished.
- 3. Billing for services: Under the exception, the ancillary services must be billed by one of the following -
 - a. The physician who performed or supervised the service;
 - b. The group practice under a billing number assigned to the group of which the physician supervising or performing the service is a member;
 - c. The group practice if the supervising physician is a "physician in the group practice" under a billing number assigned to the group;
 - d. An entity wholly owned by the physician performing or supervising the service or by that physician's group practice under the billing number for the entity or the billing number assigned to the physician or the group practice; or
 - e. An independent third party billing company acting as an agent of the physician, group practice, or certain entities under the billing number for the physician, group practice, or entity.
- C. DME covered by the in-office ancillary services exception includes canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors that meet the following conditions:
 - 1. The patient requires the item to ambulate or depart from the physician's

office, or the item is blood glucose monitor that is furnished by a physician or employee of the physician or group practice that also furnishes outpatient diabetes self-management training to the patient;

2. The item is furnished in a building that meets the "same building" requirements for the exception as part of the treatment for the specific condition for which the physician-patient encounter occurred;
3. The physician who ordered the DME, a physician in the group practice or an employee of the physician or group practice personally furnishes the item;
4. The physician or group practice furnishing the DME meets the DMS supplier standards;
5. The arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission; and
6. All other requirements of the in-office ancillary services exception have been met.

V. EXCEPTIONS FOR PHYSICIAN RECRUITMENT AND RETENTION.

A. Under the Phase II Rule, the exceptions for physician recruitment and physician retention have undergone significant modifications from the proposed rule. These changes include:

1. The focus has shifted from the relocation of the physician's *residence* to the relocation of the physician's *practice*;
2. Residents and physicians who have been in practice for less than one year will not be considered to have an established practice and will therefore be eligible under the physician recruitment exception regardless of whether or not the physician actually moves his or her practice location;
3. Federally qualified health centers ("FQHCs") are allowed the physician recruitment exception on the same basis as hospitals;
4. Recruitment payments made through existing medical groups in connection with the recruitment of a new physician are covered under certain circumstances;
5. Limited retention payments made to physicians with practices in health professionals shortage areas ("HPSAs") are allowed; and
6. The Interim Final Regulations modify the language regarding a recruited physician's ability to establish staff membership at other hospitals.

- B. Specifically, the requirements of the recruitment exception are now as follows:
1. Direct payments to the recruited physician may be made by the hospital or FQHC if:
 - a. The recruited physician will relocated his or her practice to the geographic area served by the hospital. The geographic area is composed of the lowest number of contiguous zip codes from which the hospital draws at least 75% of its patients;
 - b. The recruited physician moves his or her practice at least twenty-five miles *or* the physician's new practice must derive at least 75% of its revenues from professional services furnished to patients not seen by the physician during the prior three years (or, for the initial year, there is a reasonable expectation that 75% of revenues will be so generated).
 - c. The arrangement is set out in writing and signed by the parties;
 - d. The arrangement may not be conditioned on the physician's referral of patients to the hospital nor may the amount of the recruitment payment be based on the actual or anticipated value or volume of referrals; and
 - e. The recruited physician must be allowed to establish staff privileges at other hospitals and refer business to other entities, except as restricted under an employment or services contract, or, potentially, an economic credentialing provision.
 2. In addition to the above requirements, the following conditions must be met for a hospital or FQHC to make recruitment payments to the physician indirectly through another physician or a group practice, or directly to the physician to join an existing physician or group practice:
 - a. The written agreement must be signed by the party to whom the payments are directly made;
 - b. Except for the actual costs incurred by the physician or group practice, the remuneration must be passed directly through and remain with the recruited physician;
 - c. In the case of an income guarantee arrangement, the costs allocated by the physician or group practice to the recruited physician cannot exceed the actual additional incremental costs attributed to the new physician;
 - d. Records of the actual costs and passed through amounts must be maintained for at least five years and be made available to HHS

upon request;

- e. The actual or anticipated value or volume of referrals by the recruited physician or the physician practice cannot be taken into account in determining the remuneration;
- f. The physician or group practice may not impose additional practice restrictions on the recruited physician other than those related to quality of care; and
- g. The arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

C. Requirements of the retention exemption are now:

- 1. The Physician must be on the hospital's medical staff;
- 2. Payment is made to retain the physician's practice in the hospital's geographic service area;
- 3. The geographic area served by the hospital is either a HPSA (without regard for the physician's specialty) or an area with a demonstrated need for the physician as determined through a Stark advisory opinion;
- 4. The arrangement is in writing, signed by the parties, and is not contingent upon the physician making referrals to the hospital;
- 5. The amount of the retention payment is not directly or indirectly determined by the volume or value of actual or anticipated referrals;
- 6. The physician must be allowed to establish staff privileges at other hospitals and refer business to other entities, except as restricted under an employment or services contract, or, potentially, an economic credentialing provision.
- 7. Physician must have a bona fide, written recruitment offer from an unrelated hospital or FQHC that specifies the remuneration being offered and that requires the physician to move his or her practice at least twenty-five miles *and* outside of the geographic area served by the hospital;
- 8. The retention payment offered by the hospital must be subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the bona fide recruitment offer;
- 9. The retention payment offered by the hospital or FQHC is limited to the lesser of (i) the amount obtained by subtracting the physician's current income from practice related services from the income the physician

would receive from comparable services in the bona fide recruitment offer over no more than twenty-four months; or (ii) the reasonable costs of the hospital to recruit a new physician to the area to replace the retained physician;

10. A retention agreement cannot be entered into between the hospital and the retained physician more than once every five years;
11. The amount and terms of the retention payment may not be altered during the term of the arrangement in any manner that takes into account the volume or value of referrals; and
12. The arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

VI. EXCEPTION FOR IMPLANTS IN AN ASC.

- A. In the Phase I Rule, the definition of DHS specifically excluded services that are reimbursed by Medicare as a part of a composite rate. Consequently, most services performed in an ambulatory surgery center ("ASC") were excluded from the general self-referral prohibition. An exception was created, however, for implants (including cochlear implants, intraocular lenses, implanted prosthetics and prosthetic devices, and implanted durable medical equipment) that are furnished by an ASC if certain conditions are met. HHS felt this exception was needed since many of the implantable items are DHS but are not bundled in the ASC composite rate.
- B. The requirements for the exception are:
 1. The implant is used by the referring physician or a member of the referring physician's group practice in an ASC with which the referring physician has a financial relationship;
 2. The implant is implanted during a surgical procedure which is paid as an ASC procedure by Medicare to the ASC where the procedure is performed;
 3. The arrangement does not violate the anti-kickback statute; and
 4. The billing and claims submission for the implant does not violate State or Federal laws.
- C. The ASC implant exception applies *only* if the ASC is the entity furnishing the implant and the ASC bills for the implant. If a physician bills for the implant, another exception must be met to avoid the Stark prohibitions.

VII. EXCEPTION FOR INTRA-FAMILY REFERRALS.

- A. A new, very narrow exception was created in the Phase II Rule for referrals for DHS made by a family member of the DHS provider or to an entity providing DHS with which the immediate family member has a financial relationship, if the following conditions are met:
1. The patient who is referred for services lives in a rural area;
 2. No other person or entity is available to furnish the services in a timely manner in light of the patient's condition within twenty-five miles of the patient's residence;
 3. In the case of patients who receive services where they reside (such as patient who receives home health services), no other person or entity is available to provide the services in a timely manner in light of the patient's condition; and
 4. The arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.
- B. The referring physician or the immediate family member is required to make reasonable inquiries into the availability of alternative service providers within a twenty-five mile radius of the patient's residence. Reasonable inquiries can include consulting telephone and professional association directories or performing an internet search. A physician is not allowed to take into account the quality of the available services. In other words, the physician cannot make an intra-family referral because he or she is dissatisfied with the quality of services provided by another available service provider.

VIII. EXCEPTION FOR MEDICAL STAFF INCIDENTAL BENEFITS.

- A. In the Phase I Rule, HHS added an exception for incidental benefits provided by a hospital to its medical staff. That exception has been modified somewhat by the new Interim Final Regulations. Primarily, the exception has been expanded to allow other types of health care entities with bona fide medical staffs to provide incidental benefits on the same terms and conditions as hospitals. In addition, the \$25 limit on each benefit provided to a medical staff member will be adjusted annually for inflation.

The benefits must still be in the form of items or services (such as parking and low-cost meals) and not in the form of cash or cash equivalents, and the benefits must be provided on the facility's campus. However, compensation in the form of pagers, two-way radios or internet access used away from the campus *only* to access hospital medical records or information or to access patients or personnel on the hospital campus will be considered to be provided and used on the hospital's campus.

- B. The other requirements of the medical staff incidental benefit exception are:

1. The compensation must be *provided* to (but not necessarily accepted by) all members of the medical staff practicing in the same specialty without regard to the volume or value of referrals to the hospital;
2. Except for identification of medical staff members on a hospital web site or in advertising, the compensation is provided only during periods when the medical staff member is making rounds or engaged in other services or activities that benefit the hospital or its patients;
3. The compensation must be reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital;
4. The compensation may not be determined in any manner that takes into account the value or volume of referrals or other business generated between the parties; and
5. The arrangement cannot violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

IX. EXCEPTION FOR COMMUNITY-WIDE HEALTH INFORMATION SYSTEMS.

- A. The Phase II Rule creates a new exception for a hospital to provide information technology items and services (including both hardware and software) to a physician to participate in a community-wide health information system designed to enhance the overall health of the community. The service and items must be dedicated to use in connection with hospital services provided to the hospital's patients.
- B. The other requirements of this new exception are:
 1. The items and services are available as necessary to enable the physician to participate in the community-wide health information system and are principally used by the physician a part of such a system. The provision of the items and services cannot be provided in any manner that takes into account the value or volume of referrals or other business generated by the physician;
 2. The community-wide health information system is available to all providers, practitioners, and residents of the community who desire to participate; and
 3. The arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

X. EXCEPTION FOR PROFESSIONAL COURTESY.

- A. The Phase II Rule creates a new exception for items or services provided as a

professional courtesy.

- B. In response to comments supporting an exception for the "long standing tradition" of professional courtesy that remains a "wide spread practice", this exception was created for free or discounted health care items or services provided to a physician or his or her immediate family members or office staff.
- C. The preamble notes that regulations should not be construed as requiring or encouraging professional courtesy arrangements.
- D. The exception may be of limited value since some professional courtesy arrangements may violate the anti-kickback statute or the civil monetary penalties law.
- E. Private insurers may also take issue with professional courtesy that involves coinsurance waivers.
- F. The exception specifically provides that professional courtesy offered by an entity to a physician or the physician's immediate family member or office staff does not constitute a "financial relationship" if:
 - 1. Professional courtesy is offered to all physicians on the entity's bona fide medical staff or in the entity's local community or service area without regard to the volume or value of referrals or other business generated between the parties;
 - 2. The entity routinely offers the health care items and services provided as professional courtesy;
 - 3. The entity's professional courtesy policy is in writing and approved in advanced by the entity's governing body;
 - 4. Professional courtesy is not offered to a physician (or immediate family member) who is a Federal health care beneficiary, unless there is a good faith showing of financial need;
 - 5. The insurer is informed in writing if the professional courtesy involves a whole or partial reduction of any coinsurance obligation; and
 - 6. The arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

XI. TEMPORARY NONCOMPLIANCE EXCEPTION.

- A. A new, although very limited exception for arrangements that have unavoidably and temporarily fallen out compliance with another exception was created under the Phase II Rule.

- B. This new exception applies where:
 - 1. The financial relationship between the entity and the referring physician fully complied with another exception for one hundred and eighty (180) days preceding the date of noncompliance;
 - 2. The financial relationship fell out of compliance with the exception for reasons beyond the control of the entity, and the entity has taken prompt steps to rectify the noncompliance; and
 - 3. The financial relationship does not violate the anti-kickback statute, and the claim or bill otherwise complies with all applicable Federal and State laws, rules, and regulations.
- C. The exception only applies to designated health services furnished during the period of time it takes to rectify the noncompliance, which must not exceed ninety (90) consecutive calendar days following the date the financial relationship became noncompliant.
- D. An entity may only use this exception once every three (3) years with respect to the same referring physician.
- E. The exception does not apply to an arrangement that previously complied with the exceptions for non-monetary compensation up to three hundred dollars (\$300) or incidental medical staff benefits.

XII. GROUP PRACTICE ARRANGEMENTS WITH A HOSPITAL.

- A. The Phase II Rule includes a new, limited exception for certain group practice arrangements with hospitals under which the group practice provides the designated health services, which are billed for by the hospital.
- B. Only compensation arrangements that began before and have continued without interruption since December 19, 1989 qualify for this exception of a compensation arrangement from the definition of a "financial relationship".
- C. In addition, to qualify for this exception, the arrangement must meet the following conditions:
 - 1. For services provided to inpatients of the hospital, the arrangement must be pursuant to section 1861(b)(3) of the Act.
 - 2. With respect to the designated health services covered under the arrangement, the practice group must provide seventy five percent (75%) of such services provided to the hospital's patients.
 - 3. The arrangement must be in writing, specifying the services furnished and the compensation for such services.

4. The compensation paid over the term of the agreement must be consistent with fair market value, and the compensation per unit of service must be set in advance and not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.
5. The compensation under the agreement must be commercially reasonable even if no referrals were made to the entity.

XIII. ADDITIONAL INFORMATION.

For further information, visit CMS's website at:

<http://www.cms.hhs.gov/medlearn/refphys.asp>

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