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following cataract surgery that meet the following conditions:

(1) The eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in §410.36(a)(2)(ii) and §414.228 of this chapter, respectively.

(2) The arrangement for the furnishing of the eyeglasses or contact lenses does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(3) Billing and claims submission for the eyeglasses or contact lenses complies with all Federal and State laws and regulations.

[66 FR 959, Jan. 4, 2001]

§411.356 Exceptions to referral prohibitions related to ownership or investment interests.

For purposes of §411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that may be purchased on terms generally available to the public and that meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; or

(ii) Traded under an automated inter-dealer quotation system operated by the National Association of Securities Dealers.

(2) In a corporation that had—

(i) Until January 1, 1995, total assets at the end of the corporation's most recent fiscal year exceeding \$100 million; or

(ii) Stockholder equity exceeding \$75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal

Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding \$75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities:

(1) A laboratory that is located in a rural area (that is, a laboratory that is not located in an urban area as defined in §412.62(f)(1)(ii) of this chapter) and that meets the following criteria:

(i) The laboratory testing that is referred by a physician who has (or whose immediate family member has) an ownership or investment interest in the rural laboratory is either—

(A) Performed on the premises of the rural laboratory; or

(B) If not performed on the premises, the laboratory performing the testing bills the Medicare program directly for the testing.

(ii) Substantially all of the laboratory tests furnished by the entity are furnished to individuals who reside in a rural area. Substantially all means no less than 75 percent.

(2) A hospital that is located in Puerto Rico.

(3) A hospital that is located outside of Puerto Rico if one of the following conditions is met:

(i) The referring physician is authorized to perform services at the hospital, and the physician's ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital.

(ii) Until January 1, 1995, the referring physician's ownership or investment interest does not relate (directly or indirectly) to the furnishing of clinical laboratory services.

§411.357 Exceptions to referral prohibitions related to compensation arrangements.

For purposes of §411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if there is a rental or lease agreement that meets the following requirements:

(1) The agreement is set out in writing and is signed by the parties and

specifies the premises covered by the lease.

(2) The term of the agreement is at least 1 year.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the lease are set in advance and are consistent with fair market value.

(5) The charges are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) A rental or lease agreement is set out in writing and signed by the parties and specifies the equipment covered by the lease.

(2) The equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee.

(3) The lease provides for a term of rental or lease of at least 1 year.

(4) The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are 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 lease would be commercially reasonable even if no referrals were made between the parties.

(c) *Bona fide employment relationships.* Any amount paid by an employer to a

physician (or immediate family member) who has a bona fide employment relationship with the employer for the provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.

(3) The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(d) *Personal service arrangements.* (1) *General.* Remuneration from an entity under an arrangement to a physician or immediate family member of the physician, including remuneration for specific physicians' services furnished to a nonprofit blood center, if the following conditions are met:

(i) The arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) The arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity.

(iii) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

(iv) The term of the arrangement is for at least 1 year.

(v) The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(vi) The services to be furnished under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

(2) *Physician incentive plan exception.* In the case of a physician incentive plan between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled in the entity.

(ii) In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary under section 1876(i)(8)(A)(ii) of the Act, the plan complies with any requirements the Secretary has imposed under that section.

(iii) Upon request by the Secretary, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements of paragraph (d)(2) of this section.

(3) Until January 1, 1995, the provisions in paragraph (d)(1) and (2) of this section do not apply to any arrangements that meet the requirements of section 1877(e)(2) or section 1877(e)(3) of the Act as they read before they were amended by the Omnibus Budget Reconciliation Act of 1993 (Public Law 103-66).

(e) *Physician recruitment.* Remuneration provided by a hospital to recruit a physician that is intended to induce the physician to relocate to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

(1) The arrangement and its terms are in writing and signed by both parties.

(2) The arrangement is not conditioned on the physician's referral of patients to the hospital.

(3) The hospital does not determine (directly or indirectly) the amount or value of the remuneration to the physician based on the volume or value of any referrals the physician generates for the hospital.

(4) The physician is not precluded from establishing staff privileges at another hospital or referring business to another entity.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, if all of the conditions set forth in paragraphs (c)(2) and (c)(3) of this section are met with respect to an entity in the same manner as they apply to an employer. There can be no additional transactions between the parties for 6 months after the isolated transaction, except for transactions which are specifically excepted under the other provisions in §§ 411.355 through 411.357.

(g) *Arrangements with hospitals.* (1) Until January 1, 1995, any compensation arrangement between a hospital and a physician or a member of a physician's immediate family if the arrangement does not relate to the furnishing of clinical laboratory services; or

(2) Remuneration provided by a hospital to a physician if the remuneration does not relate to the furnishing of clinical laboratory services.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under which clinical laboratory services are provided by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services provided to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before December 19, 1989, and has continued in effect without interruption since then.

(3) With respect to the clinical laboratory services covered under the arrangement, substantially all of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with an agreement that is set out in writing and that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(i) *Payments by a physician.* Payments made by a physician—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for other items or services that are furnished at a price that is consistent with fair market value.

(j) [Reserved]

(k) *Non-monetary compensation up to \$300.* Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of \$300 per year, if all of the following conditions are satisfied:

(1) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(2) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

(3) The compensation arrangement does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in §411.351) for the provision of items or services by the physician (or an immediate family member) or group

practice to the entity, if the arrangement is set forth in an agreement that meets the following conditions:

(1) It is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement.

(2) It specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.

(3) It specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, be consistent with fair market value, 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.

(4) It involves a transaction that is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.

(5) It meets a safe harbor under the anti-kickback statute in §1001.952 of this title, has been approved by the OIG under a favorable advisory opinion issued in accordance with part 1008 of this title, or does not violate the anti-kickback provisions in section 1128B(b) of the Act.

(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a State or Federal law.

(m) *Medical staff incidental benefits.* Compensation in the form of items or services (not including cash or cash equivalents) from a hospital to a member of its medical staff when the item or service is used on the hospital's campus, if all of the following conditions are met:

(1) The compensation is offered to all members of the medical staff without regard to the volume or value of referrals or other business generated between the parties.

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(2) The compensation is offered only during periods when the medical staff members are making rounds or performing other duties that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus.

(4) The compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital.

(5) The compensation is consistent with the types of benefits offered to medical staff members—

(i) By other hospitals within the same local region; or

(ii) If no such hospitals exist within the same local region, by comparable hospitals in comparable regions.

(6) The compensation is of low value (that is, less than \$25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value).

(7) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(8) The compensation arrangement does not violate the Federal anti-kickback provisions in section 1128B(b) of the Act.

(n) *Risk sharing arrangements.* Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physicians association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the Federal anti-kickback statute, section 1128B(b) of the Act, or any law or regulation governing billing or claims submission. For purposes of this paragraph (n), "health plan" and "enrollees" have the meanings ascribed to those terms in § 1001.952(l) of this title.

(o) *Compliance training.* Compliance training provided by a hospital to a physician (or the physician's immediate family member) who practices in

the hospital's local community or service area, provided the training is held in the local community or service area. For purposes of this paragraph (o), "compliance training" means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, reporting) or specific training regarding the requirements of Federal health care programs (for example, billing, coding, reasonable and necessary services, documentation, unlawful referral arrangements).

(p) *Indirect compensation arrangements.* Indirect compensation arrangements, as defined in § 411.354(c)(2), if all of the following conditions are satisfied:

(1) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided not taking into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.

(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(3) The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.

[60 FR 41978, Aug. 14, 1995, as amended at 66 FR 961, Jan. 4, 2001]

§ 411.360 Group practice attestation.

(a) Except as provided in paragraph (b) of this section, a group practice (as defined in section 1877(h)(4) of the Act and § 411.351) must submit a written statement to its carrier annually to attest that, during the most recent 12-month period (calendar year, fiscal year, or immediately preceding 12-month period) 75 percent of the total patient care services of group practice