

§411.356

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performed in the same ASC where the implant is furnished.

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

(4) Billing and claims submission for the implants complies with all Federal and State laws and regulations.

(5) The exception set forth in this paragraph (f) does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to and implanted in the patient.

(g) *EPO and other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility.* EPO and other dialysis-related outpatient prescription drugs that are identified by the CPT and HCPCS codes on the CMS web site, <http://www.cms.gov>, and in annual updates published in the FEDERAL REGISTER and that meet the following conditions:

(1) The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph, “furnished” means that the EPO or drugs are either administered or dispensed to a patient in or by the ESRD facility, even if the EPO or drugs are furnished to the patient at home. “Dialysis-related drugs” means certain drugs required for the efficacy of dialysis, as identified on the CMS web site and in annual updates.

(2) The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(3) Billing and claims submission for the EPO and other dialysis related drugs complies with all Federal and State laws and regulations.

(4) The exception set forth in this paragraph (g) does not apply to any financial relationships between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

(h) *Preventive screening tests, immunizations, and vaccines.* Preventive screening tests, immunizations, and vaccines that are covered by Medicare and identified by the CPT and HCPCS

codes included on the CMS web site and in annual updates published in the FEDERAL REGISTER and that meet the following conditions:

(1) The preventive screening tests, immunizations, and vaccines are subject to CMS-mandated frequency limits.

(2) The preventive screening tests, immunizations, and vaccines are reimbursed by Medicare based on a fee schedule.

(3) The arrangement for the provision of the preventive screening tests, immunizations, and vaccines does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.

(4) Billing and claims submission for the preventive screening tests, immunizations, and vaccines complies with all Federal and State laws and regulations.

(5) To qualify under this exception, the preventive screening tests, immunizations, and vaccines must be covered by Medicare and must be listed on the CMS web site and in annual updates.

(i) *Eyeglasses and contact lenses following cataract surgery.* Eyeglasses and contact lenses that are covered by Medicare when furnished to patients 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.

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**§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