

§411.355

42 CFR Ch. IV (10–1–03 Edition)

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set forth in a written agreement signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient’s insurer determines the provider, practitioner, or supplier; or the referral is not in the patient’s best medical interests in the physician’s judgement.

[66 FR 958, Jan. 4, 2001]

EFFECTIVE DATE NOTE: At 66 FR 958, Jan. 4, 2001, §411.354 was added, effective Jan. 4, 2002. At 66 FR 60154, Dec. 3, 2001, the effective date of the last sentence in §411.354(d)(1) was delayed from Jan. 4, 2002, until Jan. 6, 2003. At 67 FR 70322, Nov. 22, 2002, the effective date of this sentence was further delayed until July 7, 2003. At 68 FR 20347, Apr. 25, 2003, the effective date of this sentence was further delayed until Jan. 7, 2004.

§411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

The prohibition on referrals set forth in §411.353 does not apply to the following types of services:

(a) *Physician services.* (1) Physician services as defined in §410.20(a) of this chapter that are furnished—

(i) Personally by another physician who is a member of the referring physician’s group practice or is a physician in the same group practice (as defined in §411.351) as the referring physician; or

(ii) Under the supervision of another physician who is a member of the referring physician’s group practice or is a physician in the same group practice (as defined at §411.351) as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services.

(2) For purposes of paragraph (a) of this section, “physician services” includes only those “incident to” services (as defined in §411.351) that are physician services under §410.20(a) of this chapter.

(3) All other “incident to” services (for example, diagnostic tests, physical

therapy) are outside the scope of paragraph (a) of this section.

(b) *In-office ancillary services.* Services (including certain items of durable medical equipment (DME), as defined in paragraph (b)(4) of this section, and infusion pumps that are DME (including external ambulatory infusion pumps), but excluding all other DME and parenteral and enteral nutrients, equipment, and supplies (such as infusion pumps used for PEN), that meet the following conditions:

(1) They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) An individual who is supervised by the referring physician or by another physician in the group practice, provided the supervision complies with all other applicable Medicare payment and coverage rules for the services.

(2) They are furnished in one of the following locations:

(i) The same building (as defined in §411.351), but not necessarily in the same space or part of the building, in which—

(A) The referring physician (or another physician who is a member of the same group practice) furnishes substantial physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the unrelated services may lead to the ordering of DHS;

(B) The physician services that are unrelated to the furnishing of DHS in paragraph (b)(2)(i)(A) of this section must represent substantially the full range of physician services unrelated to the furnishing of DHS that the referring physician routinely provides (or, in the case of a referring physician who is a member of a group practice, the full range of physician services that the physician routinely provides for the group practice); and

(C) The receipt of DHS (whether payable by a Federal health care program or a private payer) is not the primary reason the patient comes in contact with the referring physician or his or her group practice.

(ii) A centralized building (as defined in §411.351) that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services.

(iii) A centralized building (as defined in §411.351) that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).

(3) They must be billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) The group practice if the supervising physician is a "physician in the group" (as defined at §411.351) under a billing number assigned to the group practice.

(iv) An entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice.

(v) An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs (b)(3)(i) through (b)(3)(iv) of this section under a billing number assigned to the physician, group practice, or entity, provided the billing arrangement meets the requirements of §424.80(b)(6) of this chapter. For purposes of this paragraph (b)(3), a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

(4) For purposes of paragraph (b) of this section, DME covered by the in-office ancillary services exception means canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors, that meet the following conditions:

(i) The item is one that a patient requires for the purposes of ambulating, uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose

monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.

(ii) The item is furnished in a building that meets the "same building" requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the patient-physician encounter occurred.

(iii) The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.

(iv) A physician or group practice that furnishes the DME meets all DME supplier standards located in §424.57(c) of this chapter.

(v) The arrangement does not violate the anti-kickback statute, section 1128B(b) of the Act, or any law or regulation governing billing or claims submission.

(vi) All other requirements of the in-office ancillary services exception in paragraph (b) of this section are met.

(5) A designated health service is "furnished" for purposes of paragraph (b) of this section in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

(6) *Special rule for home care physicians.* In the case of a referring physician whose principal medical practice consists of treating patients in their private homes, the "same building" requirements of paragraph (b)(2)(i) of this section are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS contemporaneously with a physician service that is not a designated health service provided by the referring physician to the patient in the patient's private home. For purposes of paragraph (b)(5) of this section, a private home does not include a nursing, long-term care, or other facility or institution.

(c) *Services furnished by an organization (or its contractors or subcontractors) to enrollees.* Services furnished by an

organization (or its contractors or sub-contractors) to enrollees of one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization):

(1) An HMO or a CMP in accordance with a contract with CMS under section 1876 of the Act and part 417, subparts J through M of this chapter, which set forth qualifying conditions for Medicare contracts; enrollment, entitlement, and disenrollment under Medicare contracts; Medicare contract requirements; and change of ownership and leasing of facilities: effect on Medicare contracts.

(2) A health care prepayment plan in accordance with an agreement with CMS under section 1833(a)(1)(A) of the Act and part 417, subpart U of this chapter.

(3) An organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b-1 note).

(4) A qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act).

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter.

(d) *Clinical laboratory services furnished in an ambulatory surgical center (ASC) or end-stage renal disease (ESRD) facility, or by a hospice* if payment for those services is included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge, respectively.

(e) *Academic medical centers.* (1) Services provided by an academic medical center if all of the following conditions are met:

(i) The referring physician—

(A) Is a *bona fide* employee of a component of the academic medical center on a full-time or substantial part-time basis. (“Components” of an academic medical center means an affiliated medical school, faculty practice plan,

hospital, teaching facility, institution of higher education, or departmental professional corporation.);

(B) Is licensed to practice medicine in the State;

(C) Has a *bona fide* faculty appointment at the affiliated medical school; and

(D) Provides either substantial academic or substantial clinical teaching services for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center.

(ii) The total compensation paid for the previous 12-month period (or fiscal year or calendar year) from all academic medical center components to the referring physician is set in advance and, in the aggregate, does not exceed fair market value for the services provided, 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.

(iii) The academic medical center must meet all of the following conditions:

(A) All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.

(B) The relationship of the components of the academic medical center must be set forth in a written agreement that has been adopted by the governing body of each component.

(C) All money paid to a referring physician for research must be used solely to support *bona fide* research.

(iv) The referring physician’s compensation arrangement does not violate the anti-kickback statute, section 1128B(b) of the Act.

(2) The “academic medical center” for purposes of this section consists of—

(i) An accredited medical school (including a university, when appropriate);

(ii) An affiliated faculty practice plan that is a 501(c)(3) or (c)(4) of the Internal Revenue Code nonprofit, tax-

exempt organization under IRS regulations (or is a part of such an organization under an umbrella designation); and

(iii) One or more affiliated hospital(s) in which a majority of the hospital medical staff consists of physicians who are faculty members and a majority of all hospital admissions are made by physicians who are faculty members.

(f) *Implants in an ASC.* Implants, including, but not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices and implanted DME that meet the following conditions:

(1) The implant is furnished by the referring physician or a member of the referring physician's group practice in a Medicare-certified ASC (under part 416 of this chapter) with which the referring physician has a financial relationship.

(2) The implant is implanted in the patient during a surgical procedure 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

§411.356

42 CFR Ch. IV (10-1-03 Edition)

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